

EXHIBIT 13

1997 WL 34501372

Only the Westlaw citation is currently available.
United States District Court, D. Delaware.

Susan ALLEN, George P. Allen,
and Patricia Bowers, Plaintiffs,
v.

INTERNATIONAL BUSINESS
MACHINES CORPORATION, Defendant.

No. Civ.A. 94-264 JJF.

|
Dec. 18, 1997.

Attorneys and Law Firms

Robert Jacobs, Jacobs & Crumplar, Wilmington, Delaware,
for plaintiffs.

Allen M. Terrell, Jr., Frederick L. Cottrell, III, and John T.
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for defendant.

FINAL ORDER

FARNAN, J.

*1 WHEREAS, presently before the Court is Defendants'
Motion For Summary Judgment (D.I.308);

WHEREAS, the Magistrate construed this Motion as three
separate motions, including a Motion To Exclude Plaintiff's
Experts, a Motion For Summary Judgment on Plaintiff
Bowers' claim as being time-barred, and a Motion For
Summary Judgment on the issues of design defect and duty
to warn (*see* D.I. 367);

WHEREAS, on May 19, 1997, the Magistrate issued a Report
and Recommendation (D.I.367) (1) granting Defendant's
Motion To Exclude Plaintiffs' Experts as to Drs. Kroemer
and Cunitz and denying Defendant's Motion To Exclude
Plaintiffs' Experts as to Drs. Punnett and Bleeker (D.I.308);
(2) granting Defendant's Motion For Summary Judgment on
Plaintiff Bowers' claim as being time-barred (D.I.308); (3)
granting Defendant's Motion For Summary Judgment on the
issue of design defect and duty to warn; (D.I.308) and (4)
dismissing the case;

WHEREAS, Plaintiff filed Objections to the Magistrate's
Report and Recommendation (D.I.372);

WHEREAS, Petitioner objects to the Magistrate's findings of
fact and conclusions of law (D.I.372);

WHEREAS, pursuant to 28 U.S.C. § 636(b)(1), the
Court has conducted a *de novo* review of those portions
of the Report containing specified proposed findings or
recommendations to which the Plaintiff objects;

WHEREAS, the Court concludes that Plaintiff's Objections
are without merit and that the findings and conclusions
contained in the Magistrate's Report and Recommendations
are not otherwise clearly erroneous;

NOW THEREFORE, for the reasons stated in said Report and
Recommendation, IT IS HEREBY ORDERED this 18 day of
December, 1997 that:

1. The Report and Recommendation of the Magistrate
dated May 19, 1997 is adopted by the Court.
2. Defendant's Motion To Exclude Plaintiffs' Experts
(D.I.308) is GRANTED as to Drs. Kroemer and Cunitz
and DENIED as to Drs. Punnett and Bleeker.
3. Defendant's Motion For Summary Judgment on
Plaintiff Bowers' claim as being time-barred (D.I.308) is
GRANTED.
4. Defendant's Motion For Summary Judgment on the
issue of design defect and duty to warn (D.I.308) is
GRANTED.
5. Plaintiffs' case is DISMISSED.
6. The Clerk of the Court shall mail a copy of this Final
Order to all parties.

MAGISTRATE'S REPORT AND RECOMMENDATION


TROSTLE, Magistrate J.

PROCEEDINGS

On June 22, 1992, plaintiffs Patricia Bowers Mathis¹
("Bowers") and Susan and George Allen² ("Allen") filed
this product liability action against defendant International
Business Machines Corporation ("IBM") in United States

District for the Eastern District of New York, alleging that plaintiffs suffered [wrist injuries](#) solely as the result of typing on computer keyboards manufactured by defendant. D.I. 1.³ Specifically, the Complaint included claims of negligence, strict liability, loss of consortium and punitive damages. D.I. 1.⁴ IBM filed its Answer on September 21, 1992. D.I. 3. On April 20, 1994, the action was transferred to the U.S. District Court for the District of Delaware (D.I.10), with the case filed in this District on May 19, 1994. D.I. 12. Discovery thereafter ensued.

*2 On May 16, 1995, the Court signed a stipulated Order dismissing all claims based on breach of warranty and strict liability. D.I. 209. Thus, the only remaining liability claim is premised on the alleged negligence of defendant.

On October 10, 1995, the Court signed an Order setting forth the procedure for filing motions for summary judgment. D.I. 247. Defendant now moves for summary judgment, arguing that: (1) plaintiffs' proffered expert testimony is inadmissible under  [Daubert v. Merrell Dow Pharmaceuticals, Inc.](#), 113 S.Ct. 2786 (1993), as applied by [Schneck v. IBM](#), C.A. No. 92-4370(GEB), (D.N.J. June 25, 1996); (2) plaintiffs have failed to establish negligence on the part of IBM under either of the proposed theories of defective design or failure to warn; and (3) Bowers' claims are untimely. D.I. 309. Plaintiffs counter that: (1) their expert witnesses satisfy *Daubert's* criteria for admissibility of testimony; (2) IBM was cognizant of the deleterious flaws in the design of its keyboards, yet failed to correct the defects or, in the alternative, provide appropriate warnings to consumers, as did other similarly situated keyboard manufacturers; and (3) the filing of Bowers' suit was within the applicable statute of limitations, as evidenced by her medical records and controlling case law. D.I. 322. Briefing was completed and oral argument on defendant's motion occurred on September 4, 1996. *In limine* hearings addressing the qualifications and admissibility of plaintiffs' proffered experts and their testimony were conducted on November 20, 23 and 27, and December 4 and 6, 1996.

BACKGROUND FACTS

Plaintiff Allen is a 34-year-old mother of two who now works as a part-time receptionist for The News Journal Company ("News Journal"). Allen has accomplished raising her family, including attending to household chores and pursuing hobbies to varying degrees, while working throughout in a variety of jobs. For instance, while in high school in 1978, Allen

was employed part-time by Woolco Department Store as a clerk, stocking shelves, tagging merchandise, and ringing up customers' purchases on a manual cash register of unknown manufacture. Thereafter, Allen worked part-time for several months at Mister Donut, filling donuts, lifting trays and operating a cash register of unknown origin. D.I. 311, Ex. A-688-94.

In late 1980 or early 1981, Allen assumed a position as salad maker for the restaurant Royal Exchange, primarily cutting vegetables. In 1981 or 1982, she was employed full-time⁵ as prep cook for H.A. Winstons, preparing soups and sauces, cole slaw and carrot salad. D.I. 311, Ex. A-699-702.

Allen's professional relationship with the News Journal began in 1983, when she commenced part-time employment as a clerk in the Circulation Department. In this position, Allen answered phones and hand-wrote complaints about the newspaper's delivery service, averaging between 25 and 50 calls per day. No computer was utilized in this capacity. D.I. 311, Ex. A-702-706. After several months, plaintiff changed jobs within the Department, assuming work as a verifier. As such, she used a pen and paper to complete forms after receiving calls from customers. D.I. 311, Ex. 706-708.

*3 After working approximately six months as a verifier, Allen commenced the new position of verifier/clerk, initially working five days per week, but sometime thereafter decreasing hours to four days per week. As verifier/clerk, Allen used a computer. D.I. 311, Ex. A-709-11.

In approximately 1991, Allen began experiencing pain, numbness and tingling in her hands which ultimately necessitated bilateral [carpal tunnel syndrome](#) ("CTS") releases in March and June of 1992. D.I. 311, Ex. A-713-14, Ex. A-719. After the surgery, plaintiff returned to the News Journal, first as a typist, and then in her current post as receptionist, a part-time position held since approximately November 1992.⁶ In her capacity as receptionist, Allen answers telephone calls and handwrites messages. She recently has resumed typing. D.I. 311, Ex. A-720-21, 774-75. Plaintiff denies additional [injury to her wrists](#) other than a winter 1994 sprain to her right wrist due to a fall on the ice. D.I. 311, Ex. A-723-24.

As previously noted, besides her professional employment, Allen has been raising a family, for whom she did most of the cooking. Plaintiff's outside hobbies and interests include

gardening and bowling in a league for several years. D.I. 311, Ex. A-715-17.

Plaintiff Bowers is a 50-year-old mother of four currently working as a verifier/clerk for the News Journal. D.I. 311, Ex. A-760-61. Like Allen, Bowers has raised a family while working in a number of different jobs throughout the years, commencing her employment as a part-time housekeeper at nine years of age. At age 12, Bowers began work at a mushroom factory, picking mushrooms. Two years later, she switched to canning the mushrooms. D.I. 311, Ex. A-726-29.

After marriage, Bowers took a hiatus from the workforce to raise her children, returning in 1972 to part-time work as floor person and cashier for J.C. Penneys, with whom she remained until 1980. D.I. 311, Ex. A-730-32. While with that store, plaintiff used a “very old standard type of [cash] register [which] was nothing to my knowledge like IBM or anything. It just had regular keys that you would hit for ringing up a sale.” D.I. 311, Ex. A-731.

Bowers next job was as a part-time customer service representative and cashier for Strawbridge and Clothier, a position held until she rejoined J.C. Penneys in 1989. D.I. 311, Ex. A-733-35. She could not recall the manufacturer of Strawbridge's “electronic-type” cash register. D.I. 311, Ex. A-734.

In 1981, plaintiff Bowers also began weekend work in the Circulation Department at the News Journal, answering telephone calls from customers, and writing down their orders and comments/complaints. Her work hours and responsibilities ultimately increased. In 1985, Bowers started to use a computer of unknown manufacture at her job. D.I. 311, Ex. A-734, Ex. A-740-45.

Plaintiff Bowers first noticed symptoms associated with [carpal tunnel syndrome](#) in her hands and wrists in 1989, characterizing the sensations as “aching,” “tingling” and “numbness,” progressing to “severe pain” which woke her up at night. D.I. 311, Ex. A-756. She consulted an HMO about the complaints on March 10, 1990 and ultimately underwent bilateral CTS surgery. Since that time, she has returned to work as a customer service representative with the News Journal, and continues to use a computer in her job. D.I. 311, Ex. A-758-61.

*4 Although Bowers attributes her CTS symptoms to her utilization of IBM computer equipment at the newspaper, she

also worked an unidentified cash register at Acme Markets for approximately two years (1992 until 1994), until she left the position due to a back injury resulting from a fall at the News Journal. D.I. 311, Ex. A-736-39, Ex. A-772, A-781. Like Allen, she has pursued a variety of hobbies/activities involving extensive hand movement, including gardening, every day meal preparation and bowling. Bowers also is an accomplished seamstress, having learned to sew at approximately age 15, sewing daily both by machine and by hand. D.I. 311, Ex. A-746-54.


Both plaintiffs argue that their CTS impairments are a result of defendant's negligence, where IBM's keyboards used by plaintiffs were of a defective design, and the company further failed to warn of possible injuries as a result of their use. D.I. 2. Plaintiffs also contend that there is no “precise moment of injury,” but rather that the injuries represent a “cumulative and prolonged process.” D.I. 2.



IBM counters that the keyboards at issue did not proximately cause plaintiffs' medical problems, that the company did not have a duty to warn of any consequences of use of the computer equipment, and that Bowers' claim is precluded by the applicable statute of limitations, where her symptoms were discernable and in fact reported over two years prior to the filing of this action. D.I. 309, 334.



STANDARDS OF REVIEW

Summary Judgment



[Federal Rule of Civil Procedure 56\(c\)](#) provides that a party is entitled to summary judgment where “the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law.” Although the party seeking summary judgment always bears the initial responsibility of informing the Court of the basis for its motion, and identifying those portions of the pleadings, papers and documents on file, including affidavits, which demonstrate the absence of a genuine issue of material fact, where the non-moving party opposing summary judgment has the burden of proof at trial on the issue for which summary judgment is sought, he must then make a showing sufficient to establish the existence of an element essential to his case.



 [Celotex Corp. v. Catrett](#), 477 U.S. 317, 322 (1986). In other words, that “... there are any genuine factual issues that properly can be resolved only by a finder of fact because


they may reasonably be resolved in favor of either party.”
 *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (emphasis added). If the non-moving party fails to make such a showing, then the moving party is entitled to judgment as a matter of law.  *Celotex Corp.*, 477 U.S. at 322–23.



Factual disputes that are irrelevant or unnecessary will not be counted.  *Anderson*, 477 U.S. at 248. The mere existence of a scintilla of evidence in support of the non-moving party will not prevent the grant of a motion for summary judgment; there must be enough evidence to enable a jury to reasonably find for the non-moving party on that issue.  *Id.* at 249. Mere speculation or conjecture by the non-moving party clearly cannot preclude the granting of summary judgment. Thus, a court may render summary judgment as a matter of law only in those instances where there are no issues of fact and no conflicting inferences. *Id.*





1. Admissibility of Expert Testimony







*5 In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the Supreme Court delineated the standards and reasoning applied in determining the admissibility of expert scientific testimony.  113 S.Ct. 2786 (1993). The Third Circuit has interpreted *Daubert* as characterizing the district court's role as that of “gatekeeper,” ensuring that the methodology upon which the expert opinion is based is reliable; that is, that the expert's conclusion is premised upon the methods and principles of science.  *In re Paoli Railroad Yard PCB Litigation*, 35 F.3d 717, 732 (3rd Cir.1994) (“*Paoli II*”), cert. denied sub nom., 115 S.Ct. 1253 (1995).

Rule 702 of the Federal Rules of Evidence, which governs testimony by experts, requires that: (1) the proffered witness must be an expert (qualified); (2) the expert must testify to scientific, technical or specialized knowledge (reliable); and (3) the expert's testimony must assist the trier of fact (relevance).⁷  *United States v. Velasquez*, 64 F.3d 844, 849 (3rd Cir.1995) (citing  *Paoli II*, 35 F.3d at 741–42). Federal Rule of Evidence 104(a) mandates that district courts make preliminary determinations “concerning the qualification of a person to be a witness, [and] ... the admissibility of evidence.”








Id. (citing  *Daubert*, 113 S.Ct. at 2796). Thus, a district court faced with a proffer of expert testimony must make a preliminary determination of all of the aforementioned elements of Fed.R.Evid. 702, in an effort to ensure both


the reliability and relevance of the expert testimony. *Id.* (citing  *Daubert*, 113 S.Ct. at 2795–96;  *United States v. Downing*, 753 F.2d 1224, 1237 (3rd Cir.1995)).

Requisite one of Fed.R.Evid. 702, that the proposed witness be an expert, has been construed liberally by the Third Circuit.  *Velasquez*, 64 F.3d at 849 (citing  *Paoli II*, 35 F.3d at 741). In fact, this Circuit has “held that a broad range of knowledge, skills, and training qualify an expert as such,” and has “eschewed imposing overly rigorous requirements of expertise.” *Id.* (quoting  *Paoli II*, 35 F.3d at 741). See also  *Hammond v. International Harvester Co.*, 691 F.2d 646, 653 (3rd Cir.1982) (an engineer with sales experience in automotive and agricultural equipment, who also taught high school automobile repair, was permitted to testify in a products liability case involving tractors). However, the level of expertise may affect the reliability of an expert's opinions under the second and third elements of Rule 702.

Rule 702's second requirement, that the expert testify to scientific, technical or other specialized knowledge, is designed to ensure the trustworthiness or reliability of the expert's testimony.  *Velasquez*, 64 F.3d at 849. Under *Daubert*, a district court presented with a proffer of expert “scientific” testimony must make a “preliminary assessment of whether the reasoning or methodology of the underlying testimony is scientifically valid” by considering all factors related to the proffered testimony's reliability.⁸ *Id.* (quoting  *Daubert*, 113 S.Ct. at 2796–97). Where an expert has “good grounds” for his testimony, thus basing his opinion “on the ‘methods and procedures of science’ rather than on ‘subjected belief or unsupported speculation’,” that scientific evidence is deemed sufficiently reliable.  *Paoli II*, 35 F.3d at 742 (quoting  *Daubert*, 113 S.Ct. at 2795). The Third Circuit has specifically admonished against applying the reliability requirement too strictly, explaining that “the requirement must not be used as a tool by which the court excludes all questionably reliable evidence. The ultimate touchstone [of admissibility] is helpfulness to the trier of fact.”  *Velasquez*, 64 F.3d at 850 (quoting  *Paoli II*, 35 F.3d at 744).


*6 The final requirement of Fed.R.Evid. 702 addresses the relevancy of the evidence, ensuring that the evidence “fits” under the facts of the case—i.e., that there is a valid


connection between the “scientific research or test result to be presented (expertise) and the particular disputed factual issues in the case.”  *United States v. Downing*, 753 F.2d at 1237. See also  *Velasquez*, 64 F.3d at 850;  *Paoli II*, 35 F.3d at 742–43. Therefore, to satisfy the helpfulness standard under Rule 702, a valid scientific bridge must exist under this pertinent inquiry as a precondition for the evidence to be admissible. The fit standard requires more than bare relevance—a *prima facie* showing that the technique is reliable is insufficient.  *Paoli II* 35 F.3d at 743. To meet this requirement, the party introducing the proffered testimony must demonstrate by a preponderance of the evidence that its experts' opinions are reliable. In other words, that they are based on “good grounds.”  *Id.* at 743–44. Therefore, the *Daubert* analysis focuses “solely on the principles and methodology, and not on the conclusions” generated.  *Id.* at 744; quoting  *Daubert*, 113 S.Ct. at 2797.

Although such evidence meets the parameters of Fed.R.Evid. 702, it still must satisfy Fed.R.Evid. 403, which mandates that a district court consider whether the admission of proffered testimony might confuse or overwhelm the jury.⁹ As a result, the balancing test of probative versus judicial value of evidence under Rule 403 is particularly significant when evaluating expert testimony.  *Paoli II*, 35 F.3d at 747. As the Third Circuit commented in *Paoli II*:

[A] district court cannot exclude a scientific technique as too confusing and overwhelming simply based on its conclusion that scientific techniques by their very nature confuse and overwhelm the jury. There must be something about the particular scientific technique such as its posture of mythic infallibility that makes it especially overwhelming.

 35 F.3d at 746.¹⁰

Consequently, “in order for a district court to exclude scientific evidence, there must be something particularly confusing about the scientific evidence at issue ...” *Id.* Regarding the application of Rule 703 to the analysis required of expert testimony, in *Paoli II*, as a result of *Daubert*, the Third Circuit modified its previous holding in  *DeLuca v. Merrill Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3rd Cir.1990) (although a district judge makes a factual finding as to what data *experts* find reliable, if an expert avers that

his testimony consists of data upon which other experts in the field find reasonable, such averment was generally sufficient to survive a Rule 703 inquiry).  *Paoli II*, 35 F.3d at 747. Although a court's gatekeeping role is the primary focus of Rule 702, this purpose permeates the other Rules of Evidence. Therefore, when a trial judge is required to analyze whether an expert's data is the kind upon which other experts would reasonably rely, to satisfy Rule 703 the court now must

*7 assess whether there are good grounds to rely on this data to draw the conclusion reached by the [testifying] expert. Whether experts in the field rely on this type of data will simply continue to be part of the judge's analysis.

 *Paoli II*, 35 F.3d at 748–49.

Therefore, the dichotomy of admissibility between Rules 702 and 703 has been eliminated.

2. Delaware Statute of Limitations pertaining to Personal Injury Actions

According to 10 Del. C. § 8119, the statute addressing time limitations for the filing of personal injury claims,

No action for the recovery of damages upon a claim for alleged personal injuries shall be brought after the expiration of 2 years from the date upon which it is claimed that such alleged injuries were sustained; subject, however, to the provisions of § 8127 of this title.

DISCUSSION

I. Is plaintiff Bowers' personal injury claim timely under the applicable statute of limitations?

As noted, in Delaware the statute of limitations applicable to personal injury claims provides that all such actions for

recovery must be brought within 2 years from the date upon which it is claimed that the alleged injuries were sustained. 10 Del. C. § 8119. In light of this time limitation, defendant argues that Bowers' claim is barred where the evidence indicates that she experienced symptoms in her hands and wrists as early as March 10, 1990, but did not file her complaint against IBM until June 22, 1992. D.I. 309. Plaintiffs maintain that Bowers' current action falls within the confines of 10 Del. C. § 8119, as interpreted by the Delaware Supreme Court in *Collins v. Pittsburgh Corning Corporation*, because the statutory period began to run when Bowers was chargeable with the knowledge that her condition was attributable to the repetitive use of the IBM computer. 673 A.2d 159 (Del.1996). According to Bowers, she became cognizant of that fact only after a July 26, 1990 consultation with her neurosurgeon, Dr. Magdy Boulos ("Boulos"), and therefore, the statutory period began to toll as of the date of that examination. D.I. 322 at 50.

Plaintiff Bowers incorrectly applies the provisions of 10 Del. C. § 8119, misinterpreting the relevant case law. In *Layton v. Allen*, the Delaware Supreme Court found the plaintiff's 1966 medical malpractice claim timely, where in 1965, the plaintiff first experienced pain caused by a hemostat allegedly negligently left in her abdomen during a 1958 surgery. 246 A.2d 794, 798 (Del.1968). The court held that:

... when an inherently unknowable injury, such as is here involved, has been suffered by one blamelessly ignorant of the act or omission and injury complained of, and the harmful effect thereof develops gradually over a period of time, *the injury is 'sustained' under [section] 8118 when the harmful effect first manifests itself and becomes physically ascertainable.* Translated in the terms of this case, we hold that the limitations period commenced to run when the plaintiff first experienced pain caused by the unknown foreign object.

*8 *Id.* (emphasis added).

Thus, in *Layton*, the plaintiff's claim was not time barred where she first experienced the pain associated with defendant's negligence and filed her claim within two years thereafter. Delaware courts expounding upon the principle espoused by *Layton* consistently have held that a plaintiff's first manifestation of pain—rather than the date of a definitive diagnosis—triggers the statute of limitations clock. See *Greco v. University of Delaware*, 619 A.2d 900, 905 (Del.Supr.1993); *Cole v. Delaware League for Planned Parenthood, Inc.*, 530 A.2d 1119, 1124 (Del.1987) ("For the statute of limitations to begin to run, plaintiff is not required to have knowledge of a causal relationship between the initial injury and the defendants' tortious conduct"). Indeed, the court in *Collins v. Wilmington Medical Center* specifically rejected the theory that the Section 8119 statute of limitations would not commence until a diagnosis was made:

[C]ommencement of the running of the statute does not depend on when a diagnosis is made or a "cure" effected. If it did, the statute would never start in some cases. The statute starts, rather, when a harmful effect first manifests itself and becomes physically ascertainable. In short, manifestation of the problem, not its cure, is the test under *Layton*.

319 A.2d 107, 108 (Del.Supr.1974).¹¹

Plaintiff Bowers clearly experienced the symptoms now at issue more than two years prior to the June 22, 1995 filing date of the complaint, as evidenced by the following colloquy between Bowers and defendant's counsel at her deposition:

Q: When was the first time that you were aware of any type of symptoms in your wrists or hands?

A: What year are you saying?

Q: Yes.

A: Probably around '89. You know how well—with myself, when I'm in pain I'll endure it for a while before I think it's something serious.

D.I. 310, Ex. A-755.

This testimony is confirmed by Bleeker in her November 11, 1994 occupational neurology evaluation, wherein the doctor recorded that Bowers “began experiencing symptoms in her hands in 1989,” (D.I.310, Ex. A–113), and is also confirmed by Bowers' neurosurgeon, Magdy Boulos, in a follow-up letter after her July 26, 1990 examination.¹² Indeed, the June 20, 1990 physician progress notes from Bowers' HMO indicate that plaintiff had been experiencing “arm numbness” including “1 month [history] of intermittent lower left arm and hand paresthesias when waking from sleep or after brushing hair,” with similar symptoms in the right arm. D.I. 310, Ex. A–799. Moreover, in March 10, 1990 HMO progress notes, Bowers' physician raised the possibility of “DeQuervain” or “Tenosynovitis.” D.I. 310, Ex. A–780.



The fact that Bowers may have been diagnosed *definitively* within the two-year period prior to her filing this action is *not* the controlling factor according to relevant case law, despite plaintiff's protests to the contrary. What is of consequence is the unrefuted testimony by plaintiff herself, corroborated by the medical evidence, that plaintiff suffered discernable symptoms of her medical condition at issue *prior* to two years before this suit was filed. As such, under 10 Del. C. § 8119, plaintiff Bowers' claim is time-barred and this Court recommends that her action be dismissed.



II. Do plaintiffs' proposed witnesses satisfy the *Daubert* test?

*9 Plaintiffs submit four liability expert witnesses to establish that (1) the existence of design defects in IBM's keyboards at issue (2) caused plaintiffs' repetitive stress injuries, which (3) could have been prevented had proper warnings as to the use of the *inherently dangerous* instrumentalities been provided, as IBM was obliged to so do. To this end, Drs. Karl Kroemer (“Kroemer”)¹³ and Robert Cunitz (“Cunitz”) would proffer on, respectively, the state-of-the-art and design defects in the keyboards and the appropriate warnings and instructions negligently omitted by IBM, while Drs. Margit Bleeker and Laura Punnett addressed the element of causation. As provided by the Court, with concurrence of the parties, Drs. Kroemer and Punnett's depositions taken during the similar *Schneck* action now serve as their proffered expert testimony, supplemented as necessary to address the specifics of this action. *Schneck, C.A. No. 92–4370(GEB)*, (D.N.J. June 25, 1996).¹⁴

The *Schneck* case stands as precedent on the issues correctly raised.¹⁵ In *Schneck*, the plaintiff allegedly developed bilateral *carpal tunnel syndrome* after working on IBM punch and data entry machines. Her action against IBM was premised upon the theories of strict liability, negligence and breach of warranty, with testimony from expert liability witnesses offered. As here, IBM moved for summary judgment, arguing in part that plaintiff's experts were inadmissible under *Daubert*. Focusing on Fed.R.Evid. 702's expert witness testimony requirements, the *Schneck* court analyzed whether the proffered experts could provide “scientific, technical, or other specialized knowledge” to “ensure the reliability or trustworthiness of the expert's testimony,” finding that plaintiff's retained experts on the issues of design defect and failure to warn (Drs. Karl Kroemer and Samuel Glucksberg, respectively) did not satisfy *Daubert's* scrutiny. *Schneck* at 15, 25 (citation omitted). Specifically, the *Schneck* court concluded, upon conducting an *in limine* hearing, that “there is no ‘connection between the scientific research and test result to be presented, and particular disputed factual issues in the case.’” *Id.* at 25 (citation omitted).

While this Court was inclined to find similarly in the case at bar, based upon submitted materials, plaintiffs maintained that an *in limine* hearing is essential prior to the rendering of a decision regarding the qualifications and admissibility of the testimony of plaintiffs' expert witnesses. And, indeed, upon careful review of the parties' arguments and relevant case law on the matter, the Court determined that while the circumstances of this action do not necessarily mandate an *in limine* hearing for the Court's exclusion of the expert testimony under Rules 702 and 703, Third Circuit case law and the principle that “discretion is the better part of valor” suggested that such a hearing at this stage of the proceeding was an appropriate action.

*10 In the interest of avoidance of a lengthy discourse on the issue, this Court cites the Third Circuit's controlling analysis of the evidentiary matter in *Paoli II*. In that case, the Third Circuit did not clearly address the need for an *in limine* hearing when testimony exclusion is based upon Rule 702. However, it did state unequivocally that Rule 403 is rarely appropriate for pre-trial exclusion, because a judge cannot ascertain potential relevance until that judge has a virtual surrogate for a trial record.  *Paoli II*, 35 F.3d at 747;  *Paoli I*, 916 F.2d at 859–60. In fact, the appellate court noted in its discussion of Rule 403 that “it is important to

determine whether the *in limine* hearing in the district court created the ‘virtual surrogate for a trial record’ that we have required before exclusion is permissible.”  *Paoli II*, 35 F.3d at 746–47. Recognizing that the Supreme Court’s analysis in *Daubert* in essence “blended” the balancing tests (confusing/overwhelming prong) of Rules 403 and 702, the *Paoli II* court held that for exclusion of scientific evidence under Rule 403, “there must be something *particularly* confusing about the scientific evidence at issue,” with “that something” being more than the complexity of such scientific evidence in general.  *Id.* at 747. Consequently, to the extent that the balancing “helpfulness” test of Rules 702 and 403 overlap, when that test is employed under Rule 702, as with under Rule 403, it would appear that an *in limine* hearing is required. And thus, while there is no doubt that this Court has been *inundated* with depositions, affidavits and expert reports relating to the proffered experts’ qualifications and the admissibility of their testimony, and upon which a reasoned decision may have been discharged, it nonetheless chose to err on the side of caution by conducting *in limine* hearings on these issues on November 20, 23 and 27, and December 4 and 6, 1996.

In light of this background and with consideration of all submitted materials and *in limine* testimony, this Court now individually addresses the merits of defendant’s motion to exclude plaintiffs’ proffered experts.

A. Dr. Karl Kroemer.

An industrial engineer, Dr. Karl Kroemer (“Kroemer”) is proffered by plaintiffs as an expert on the relationship between the design and use of keyboards and “*cumulative trauma disorders*”—defined by Kroemer as “those disorders stemming from often repeated actions whose cumulative effects finally result in an injury as well as the state-of-the-art in that regard.” D.I. 310, Ex. A–313–15. Upon purported review of the relevant literature on the subject, Kroemer concludes that “the relation between [*cumulative trauma disorders*] and design and use of keyboard devices was well established.” D.I. 310, Ex. A–352. However, during deposition testimony in the *Schneck* case as well as the December 4, 1996 *in limine* hearing, Kroemer acknowledged that even today, there is limited knowledge of this hypothesized relationship. D.I. 310, Ex. A–290–91; D.I. 359, Kroemer *In Limine* Hearing, Dec. 4, 1996. In fact, Kroemer wrote a January 5, 1993 letter, referred to in the deposition transcript, which states in relevant part: “[t]here are many different possible causes for [*cumulative trauma*

disorders], some of them related to off-duty activities, some possibly related to activities on-the-job. Of those on-the-job, keyboarding is probably the most prevalent. However, which keyboarding factors contribute under what condition is still largely unknown....” D.I. 310, Ex. A–463.

*11 Moreover, as noted in *Schneck*, while Kroemer’s conclusion includes a reference to QWERTY keyboard design, such as that of the keyboards at issue, his criticisms are *generic*; i.e., the binary key use, the arrangement (geometry) and placement of keys (including improper spacing of the keys, necessitating large force and displacement to operate), and the use of the keyboard (keyboard displacement). In support of his conclusion beyond his years of personal experience, Kroemer has cited a number of scientific, peer-reviewed articles discussing keyboard problems and proposing alternative keyboard designs which compl[y] better with the natural location and motion of fingers, such as the split keyboard.¹⁶ D.I. 352, Ex. 78. However, Kroemer failed to cite any studies which indicate that alternative keyboard designs to the QWERTY keyboard now commonly used actually serve to reduce the incidence of relevant *musculoskeletal disorders*. D.I. 352, Ex. 78.

During his deposition and *in limine* testimony for the *Schneck* case, Kroemer was examined about the methodology employed in reaching his conclusions.¹⁷ Concerning his methodology for selecting the literature upon which he based his conclusion, Kroemer provided the following description:

Q: I guess what I want to know from you is, how did you decide what to include and what not to include in Exhibits 5 [*Kroemer Report*] and 6 [*Kroemer Supp. Report*]?

A: The general issue is the design and use of keyboard and related entry devices. So such papers would be included that directly or indirectly related to this topic. Secondly, I tried to apply some judgment as to the validity of any given publication and such that it would either be contributing towards an assessment of what was known at the time or it would set certain highlights.

Q: So, as I understand it correctly, you look not only at the topic of what a paper was about, but also you read it and analyze its validity before including it in [Exhibits] 5 or 6?

A: Yes.

Q: And therefore you made some judgments as to the validity or lack of validity of what the author or authors were saying in a particular article that was on a topic that dealt with design and use of keyboard and related entry devices?

A: Yes, sir.

Q: And I also take it then that if the author's statements were valid they would be included in these summaries here, Exhibit [sic] 5 and 6, correct?

MR. PHILLIPS: Objection.

A: Valid only in the sense that they would shed a given light on a topic and perhaps regarding conclusions. But the term "valid," as I understand it, doesn't necessarily mean that I feel that the author would be correct.

D.I. 310, Ex. A-199.

Upon plaintiffs' counsel's objection, Kroemer then retracted his testimony and conceded that a paper or article was considered in his reports solely if it was "relevant." D.I. 310, Ex. A-200.¹⁸ Kroemer maintained that a publication was included in his report regardless of his views on whether the publication was correct from a scientific, engineering, or medical point of view, however, he excluded articles that were "purely journalistic." D.I. 310, Ex. A-200, A-242.

*12 During the subsequent course of his *in limine* testimony in *Schneck* directed to his state-of-the-art opinion, Kroemer was queried about the interim steps between the collection of data and his final analysis:

Q: And can you tell me, how did you get from the collection of articles, where some are in favor of that opinion, and some are against that opinion, and some are in between, how did you get from there, that body of literature, to that conclusion, what criteria did you use?

A: The criteria—

MR. MAIMON: Object to the form. Compound.

THE COURT: Sustained.

BY MR. D'AVANZO (CONTINUED):

Q: How did you—

MR. MAIMON: I have no objection to how do you—how did you get there, I—

MR. D'AVANZO: I'm going to amend the question.

THE COURT: Okay.

Q: How did you get from this body of literature, that was either supportive, or critical or non committal, or in between, with respect to your conclusion, that the relationship was well established?

A: I wish you had left out—left out the last few words, of your question.

Q: Let me try it again. Let me withdraw. How did you get from this body of literature, to your conclusion?

A: Okay. Now, keep in mind that I worked for—the first years of my professional life, in a—in a research institute that had engineers, psychologists, and physiologist, mostly, Mds.

It was quite well established then, that typing was often associated with what we call now, CTDs.

So there was no question even, in the 50's, about it. Or in the 60's. The—question is, what are the specific relations, and this is of course, a biomechanical problem, as far as I can judge. I cannot medical—judge it on a medical side, for example.

But whether you do unaccustomed farm work, or whether you do meat cutting, or whether you do keyboarding, it all involves in essence the same so to speak mechanical or biomechanical structures of the body.

So, as—as you put all that evidence together, it—it makes clear and imminent sense to say that the posture, the motion, the forces, the repetitions, the way—the frequency of—of doing it, is clearly related to an over exertion of—of parts of the human body.

Q: And can you tell me what—withdrawn. Is there a particular methodology that you utilized to go from the knowledge expressed in these articles, to your conclusion?

A: *The methodology would be—is it plausible according to what we know, about how the body reacts to repetitive exertions of that kind.*

Q: *And now, that—that criteria, or methodology that you followed, is that something that's normally followed by engineers and ergonomists? In making drawing conclusions from literature?*

A: *Well, I don't know about others, but I would think that is a—a logical and—and—and reasonable way of going about drawing conclusions.*

Schneck Op. at 18–20 (citing *Kroemer Tr.* at 43–46 (emphasis added)).

During his more recent *in limine* testimony (on both direct and cross-examination), Kroemer similarly articulated the general methodology that he would apply to a state-of-the-art search on a particular ergonomic topic and the subsequent analysis of the material selected, as well as the specific approach employed to reach his conclusions for these personal injury cases against IBM:

*13 Q: ... Let's focus in a decade of the 1980's. If one in ergonomics wished, then, to do a search of the available state-of-the-art knowledge of—in an area, how would one go about it?

A: One would try to collect all information that is relevant to the topic in question and sift through the information available with respect to what appears to be valid and important.

Q: Okay. How would one go about trying to locate the whole arena of knowledge? You know, what type of search would one do, say in the decade of the eighties?

A: If the topic is one in which one has worked before, one probably has a stock of—of information available already. If the topic would be completely new, one would probably start out with a computerized search of the literature and from there go into specific journals and articles as they become mentioned in the literature.

THE WITNESS: If the question were simply scientific and specific, one might want to limit one's self to the scientific literature. If it is a matter of the general state of knowledge, then one would go beyond the scientific

literature and include items that shed light on the topic in question.

Q: Okay. I think you said, then, that one would sift through and review. Can you explain to the Court what you mean by that?

A: I would go ahead to—in this procedure, as I find a published article, I would look at the author, at the source of printing the journal or whatever it might be. And from there, proceed to determining what the specific procedures were applied by the author, what the experimental results are, how they are described, and how they are interpreted.

A: I would include any article that provides reliable or believable or valid information.

A: If I want to determine the state-of-the-art about a topic, I would include everything, given those criteria fulfilled, regardless of what the outcome or opinion of the author is.

THE COURT: How do you determine, Doctor, and what methods or what standards do you use to determine whether an article is valid or important of the topic that you are working on?

THE WITNESS: After having determined that this is—a credible author, institution and journal published, I would go into the question, what are the experimental hypotheses, how were they tested, if subjects involved, how many, how selected. What are—how—what data are reported, how were they treated statistically, and, finally, what conclusions were drawn from—from the data in their statistical evaluation.

THE COURT: And when you go through that analysis, those standards that you use, those questions that you ask yourself, what is important for you, in your methodology, fact—what factors are important in those questions in your methodology to analyze whether an article is valid and important for your purposes?

THE WITNESS: Beyond the—the items that I already indicated—

THE COURT: I'm trying to find out those standards or those factors within those items that you would be—

for example, one of the things you said was the number of subjects that were studied. I don't know whether there's a breaking point for too little or not enough to be considered a study that you could say, yes, this would be a valid hypothesis or a valid conclusion.

***14 THE WITNESS:** That would depend on the specific experiments conducted. If you want to do a general population statement, then you probably need a large number of subjects. If you wanted to look at within subject, then you might, for instance, need a small number of subjects.

So the number of subjects as an example would depend on the specific hypotheses to be tested.

Q: ... In your mind, what is a review article, when we are talking about this area of knowledge in ergonomics?

A: A review article would be one in which several or possibly many studies or other pieces of information are compiled, reviewed, possibly abstracted, and a—in most cases, a general conclusion is given about what the overall information is on the topic that is being reviewed.

Q: Okay. And how do you apply your criteria to those types of articles?

A: Well, of course, the criteria are somewhat different now, because we don't have a report on an experimental study.

In this case, one would probably look for inclusive necessary, completeness, non-biased reporting, proper abstracting of the original articles. In other words, credibility and validity would be the main criteria.

Q: Okay.

THE COURT: Okay, Doctor. Before you go on about that, in the review article scenario that you just discussed, how do you determine credibility of that review article, since part of your analysis includes proper abstracting of original articles.

THE WITNESS: One is probably not completely naive on the topic. Even if one were, one would have to go back, in many cases, look at some of the originals that are being abstracted and reviewed, determine from there whether the reviewer has done a fair job.

However, this is quite often helped by the fact that the—the authors are—there are probably not too many authors in the field. So one has already a feeling for the reputation of the author, the reputation of the institution that the author is associated with. And if it is a published work, what publisher, what journal, does this?

There are a number of journals that specialize, for instance, in annual reviews of certain topics. In such a case, one can be almost assured that this is a solid piece of work.

D.I. 359 at 8–17.

Q: And can you give me your understanding of what peer review is?

A: Peer review usually occurs if you submit an article or other piece of work for publication in a journal, in which case the draft manuscript is reviewed by other persons in the field; that is the peers. And their recommendation is then usually used by the publisher to either accept, reject or recommend revision before publication.

THE COURT: Did you feel when you were doing that review [on the state-of-the-art knowledge of issues related to keyboard design, use and possible consequences of injury], that you were limited to cumulative stress trauma-type injuries?

THE WITNESS: No, I did not feel that I was limited. The judgment was to—was left to me.

***15 THE WITNESS:** I would include [in his reports of his conclusions] all information that would pass the criteria that we discussed earlier this morning. I would exclude pieces that would not survive that selection criteria.

THE COURT: So that whether or not cumulative stress trauma was mentioned in any report, that wasn't one of the bases you used to include or exclude?

THE WITNESS: The pure mentioning would not be sufficient. It would have to be substantiated.

Q: And so throughout this review of articles, there are articles, are there not, that do not deal with keyboards, that is, typewriter or computer keyboards per se; correct?

A: Yes. In some cases, this is the—it is true. However, the reason why they are in there, because they refer to biomechanical, or the ergonomic aspects that are directly involved in the problems associated with the operation of keyboards.

D.I. 359 at 79.

A: I would include occasionally trade journal publications like the one we are looking at, which is Rosch, R-o-s-c-h, 1984, on Page A-000422. If they would indicate—or if they would highlight the state-of-the-art, the state of knowledge, the state of technology available ...

THE COURT: ... Doctor, when you review or look over scientific journals, is it your expectation that the information contained in the scientific journals have already been reviewed for accuracy?

THE WITNESS: If it is a well-known, established journal, such as Human Factors or Ergonomics or some others, of which I know there is a critical review process going on, then my presumption would be of correctness. I don't recall ever having found it was incorrect. It could be the case. I would presume it is correct.

THE COURT: Do you operate on the same presumption when reviewing trade journals?

THE WITNESS: No, I'm not.

Q: Dr. Kroemer, I just have one question, perhaps. And that is the methodology and criteria that you utilized in doing your report and your literature review, is that a methodology or criteria that is normally followed by industrial engineers and ergonomists?

A: Which reports are you referring to?

Q: The March 1992 report and the February 1994 review of publications.

A: Of course, I can't speak for everybody else, but I would think that is a normal procedure.

Q: Isn't it true that when I asked you that question in front of Judge Brown at the Schneck hearing in August of 1995, that you told me that you didn't know about whether others utilized that criteria, but that you thought that it was a reasonable way to go about drawing conclusions?

A: You apparently have notes in front of you that I don't have. But I thought I just gave you, in essence, the same answer, even before you read from your notes.

Q: So you don't know if anyone else follows the criteria that you utilized in this case; correct?

A: That's not what I said. I said I can't speak for others; but I assume this is a method that would be used by others as well.

***16** D.I. 359 at 116–117.

With specific regard to the conclusions purported by Kroemer on design defect, the doctor described his methodology to the keyboard design critique as follows:

Q: ... Now, if a person who has your experience in keyboards and key—keyboard design is presented with a keyboard to critique with respect to any design deficiencies, how do you approach critique [on] that? On what do you rely?

A: Well, you might say certain levels of evaluation. The first one is simply a visual inspection, in terms of size, number of keys, arrangement of keys, maybe angles, slopes, whether or not there is a split and so forth.

And a second level of evaluation, then, would be followed by distinct measurements, such as of key force displacement characteristics and other issues that would not be obvious to the naked eye.

D.I. 359 at 158–59.

A: ... Having been in the field so long, it's rather difficult to try to separate out a continuous assessment procedure. But, first of all, I've seen many keyboards and I've used many keyboards, so I have, I think, a lot of experience.

The experience then relates to the issues that I have indicated before, which is zig-zag columns or—sorry—straight columns, straight rows, horizontal rows, large number of keys, keys in one row in a horizontal plan, so

forth. So these are the same issues that I have mentioned before.

Secondly, one would probably go ahead and, as appropriate, try to compare the keyboard in question with certain literature, if this is an issue. It might be a special use keyboard as opposed to a general use keyboard.

Q: We're assuming this is a very general-use PC keyboard.

A: Then I don't think I have to go to much literature, although I could go ahead and compare it with and see 100 of 1988 or something of that kind. So I would find, if needed, some reference publications to compare it to.

And then the third step, as I've said, is to take specific measurements that cannot be done by simply looking and visually examining the keyboard.

Q: Okay. And with respect to keyboard geometry, would you use the same procedure?

A: Yes, that would be very much the same procedure.

D.I. 359 at 164–65.

When Kroemer was queried by the Court about the type of measurement analysis conducted with regard to his criticisms of keyboard placement and keyboard use in the typical QWERTY keyboard, the following colloquy resulted:

THE COURT: All right. Could you please turn to item No. 4? Keyboard placement, Concern No. 4. Why are measurements taken under that circumstance?

THE WITNESS: The keyboard placement should be done in such a way that is comfortable and healthy for the operator to operate the keyboard.

A general rule would be to have the majority of the keys at about elbow height of the operator. One could look at an operator and determine in the side-view whether the keyboard is about at that angle. If one does not know who might be the potential operators, one would have to take a measurement about adjustment ranges and compare this with different elbow measurements.

*17 THE COURT: Were measurements taken—are measurements—strike that. Would the measurement analysis be applied to Concern No. 5, keyboard use?

THE WITNESS: Yes and no.

THE COURT: Okay.

THE WITNESS: There is a yes and no answer. There's some general keyboard use issues, such as does the person hold their [sic] wrists straight and as grandmother always suggested, and she was right.

So some of these are clearly identifiable by pure observation.

Others would require measurement over a period of time. For example, how long would be a working bout, how long might be rest breaks between such bouts of keyboard operation. How many key strokes were performed over a period of time.

Perhaps even how large are the actual activation forces being applied by the subject as opposed to design values, which are not necessarily the ones that operate as used.

So there are some issues that can be resolved by observation. There are some issues that need to be resolved by measurement.

D.I. 359 at 170–71.

IBM contends that Kroemer's conclusions are unreliable because: (1) his methodology was unscientific;¹⁹ (2) he was unable to cite a single study which demonstrates that the use or design of keyboards results in some injury (such as CTS, as in the case at bar); and (3) he did not describe any specific design defect in the IBM keyboard which *caused plaintiffs' injuries*. D.I. 309 at 13.

Having set forth Kroemer's methodology and with the acknowledgment that Kroemer is an expert in his field, this Court will now determine whether it satisfies *Daubert/Paoli II*, with consideration of the *Schneck* court's analysis on the matter. *See Schneck* Op. at 21–25.

(1) *Daubert/Paoli II* Factors

(i) *Does the Methodology Consist of a Testable Hypothesis?*

Defendant does not challenge the testimony of Kroemer's hypothesis, that “the relation between [cumulative trauma disorders] and design and use of keyboards as input devices was well established.” Rather, defendant argues that Kroemer's *conclusions* are unreliable, in light of his

unscientific methodology, his inability to cite a single study demonstrating that the use or design of keyboards causes some injury (such as CTS, as in the case at bar), and his further failure to describe any specific design defect in the IBM keyboard which caused plaintiffs' injuries. D.I. 309 at 13. Accordingly, this factor will weigh in favor of the admissibility of the proffered testimony.

(ii) *Has the Methodology Been Subject to Peer Review?*

At the *in limine* hearing in *Schneck*, as well as in this matter, Kroemer testified that the particular reports at issue (his pre-August 1995 reports) have not been subject to peer review. *See Schneck Op.* at 21 (citing *Kroemer Tr.* at 41); D.I. 359 at 60. Further, he was uncertain whether the methodology leading to his conclusion has been utilized or recognized by others. *Id.* (citing *Kroemer Tr.* at 45–46); D.I. 359 at 116–17. While with particular respect to design defect, several scientific articles relied upon by Kroemer were purportedly subject to peer review, Kroemer's more recent *in limine* testimony never addressed whether his analysis or methodology has been followed by others in his field.²⁰ As such, this factor militates against the admissibility of the proffered testimony.

(iii) *Is There a Known or Potential Rate of Error?*

*18 No known or potential rate of error in Kroemer's methodology has been provided and therefore, the Court cannot evaluate this element. As a result, this weighs against the admission of the proffered testimony.

(iv) *Were There Standards Controlling the Technique's Operation?*

In his analysis, Kroemer accepts the conclusions reached in the various articles collected by him and compares them with his understanding of how the body reacts to repetitive exertions of the kind described in the articles. The Court does not regard this as a “standard.” Therefore, this factor counts against the admissibility of Kroemer's proffered testimony.

(v) *Is the Methodology Generally Accepted?*

As previously discussed, Kroemer is unaware of any followers of his methodology. *See Schneck Op.* (citing *Kroemer Tr.* at 45–46); D.I. 359. Nor have plaintiffs identified any such followers. This factor thus weighs against the admissibility of his proffered testimony.

(vi) *Is There a Relationship Between the Technique and Other Methods Established to be Reliable?*

No clearly definable technique has been provided enabling this Court to ascertain the relationship between such a technique and other methods of established reliability for his analysis of state-of-the-art and design defects. Accordingly, this component weighs against the admissibility of proffered testimony.

(vii) *Are the Qualifications of the Expert Based Upon the Methodology Appropriate?*

Defendant has not challenged Kroemer's qualifications. This factor therefore supports the admission of the proffered testimony.

(viii) *Non-Judicial Uses*


No distinct parameters have been identified to determine whether Kroemer's methodology would have any application outside of the current judicial setting. As a result, this consideration also weighs against the admissibility of his proposed testimony.

(ix) *Other Factors*

As previously noted, Kroemer admitted in his deposition that scientists' current knowledge about the hypothesized relationship between keyboard design/use and [cumulative trauma disorders](#) is limited. D.I. 310, Ex. A–290–91, 463–64. Moreover, plaintiffs' proposed expert has failed to cite a single study which demonstrates that use or design of keyboards causes some injury (or, as is relevant to this case, [carpal tunnel syndrome](#)). Notwithstanding his incertitude and absence of literative support, Kroemer maintains that the “relation” between “[cumulative trauma disorders](#)” and “design and use of keyboards” is “well established.” D.I. 310, Ex. A–352. Although a finding that an expert's opinion is unreliable cannot be made merely because the concept is novel or differs from that of other experts, Kroemer nonetheless must provide a detailed rationale for reaching his firm conclusion, and in so doing, address how he overcame the aforementioned concerns. Without such evidence, this factor militates against the admissibility of the proffered testimony.



(x) *Conclusion*

*19 This Court concurs with *Schneck's* holding that the *Daubert/Paoli II* analysis weighs decisively in favor of excluding the proffered testimony. *Daubert's* standards are

clear: “the expert [must] testify to scientific knowledge—conclusions supported by good grounds for each step in the analysis—mean[ing] that *any* step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology.”  *Paoli II*, 35 F.3d at 745 (footnote omitted) (emphasis in original). In light of his unscientific methodology and inability to produce a single study demonstrating that the use or design of keyboards causes some injury (such as CTS), Kroemer's conclusions must be deemed unreliable.

(2) *Fit*

Fed.R.Evid. 702's third requirement—that the evidence is relevant or “fits” under the facts of the case—also must be satisfied before an expert's proffered testimony may meet the *Daubert* test.

In the case at bar, Kroemer's testimony has been offered for the proposition that keyboard use can cause “cumulative trauma disorders,” defined as a “collective term for syndromes characterized by discomfort, impairment, disability or persistent pain in joints, muscles, tendons and other soft tissues, with or without physical manifestations.” D.I. 310, Ex. A–314. Yet, Kroemer has offered no scientific research which proves that keyboard use can cause the medical conditions claimed in this action. Furthermore, while Kroemer did offer some specific criticisms of the generic QWERTY keyboard design and proposed what is theoretically a more ergonomically appropriate alternative (i.e., the split keyboard design), no evidence was proffered that such an alternative design actually reduces the incidence of any *musculoskeletal disorders* purportedly associated with repeated keyboard use. Accordingly, as in *Schneck*, this Court finds that Kroemer's testimony regarding the “defective” design of keyboards and its resulting adverse medical implications must be excluded, where there is no “connection between the scientific research or test result to be presented, and particular disputed factual issues in this case.”²¹  *Velasquez*, 64 F.3d at 850 (quoting  *Downing*, 753 F.2d at 1237). See also *Schneck* Op. at 25.

(d) *Conclusion*

Based on the foregoing analysis, this Court recommends Dr. Kroemer's testimony be excluded in its entirety.

B. Dr. Laura Punnett

Laura Punnett, Sc. D., is an occupational epidemiologist and ergonomist. In *Schneck*, as in the case at bar, plaintiffs offer her opinion to establish general causation between VDT (video display terminal) use and “*musculoskeletal disorders*.” While also asked to opine on causation with respect to the *Schneck* plaintiff's individual claim, Punnett serves as a “generic” expert in the case at bar, where her opinion does not specifically address either Allen's or Bower's particular assertions of injury. Indeed, Punnett's report submitted for the purposes of this action is identical to that considered in *Schneck v. IBM*, with the current parties utilizing her deposition testimony from the earlier case, supplemented by her November 27, 1996 *in limine* hearing testimony. (Punnett *In Limine* Hearing, November 27, 1997, D.I. 350).

^{*20} According to her *in limine* testimony, Punnett began her research by conducting an unbiased literature review for articles directly bearing on video display terminal use and upper extremity *musculoskeletal injury*,²² the standard operating procedure in the scientific community. Each study was then reviewed to ensure that it met the minimum quality of methodological criteria for a sound epidemiological study. To wit, Punnett considered: (1) the potential for selection and information bias; (2) whether potential confounders were measured and included in the analysis; (3) the size of the study and the statistical power involved; and (4) the nature of the contrast and exposure, and whether there was likely to be a big enough spread and exposure to plausibly show a difference in health effects, if one existed. Punnett then grouped the studies according to their “strength,” ensuring that even the weakest met the minimum threshold of the search criteria. The studies were next grouped systematically, with Punnett organizing them by body region and identifying each study's respective results for the assessed physical dimensions of exposure. D.I. 350 at 4–13.

Punnett testified that she did not conduct a meta-analysis of the studies' data—that is, “a calculation of common or pooled odds ratios or relative risk estimates” *sometimes* made by epidemiologists. D.I. 311, Ex. A–594. She did, however, examine the data of each study for its consistency and evaluated each study on its own merits. Punnett further conducted independent analyses of the internal data of the selected studies, including comparison to an external source of data. Specifically, Punnett used the set of data for the low force, low repetition group in the Silverstein papers (part of the included scientific literature) to estimate gender-

specific expected rates of disease, and then standardized the expected rate to the mix of male and female workers in each of two other prominent studies. She further calculated gender-standardized odds ratios—estimates of relative risk—for the health end point (which in one case was the hand-wrist disorders defined by symptoms and physical examination, and in two other cases was for the symptom-based case definition). A comparison of the age distribution amongst all the populations also was conducted. D.I. 350 at 23–34, 36–43.

With regard to supplemental external analyses, Punnett compared an external “background” group of people who were employed in jobs that were measured quantitatively and objectively and found to be “low” in the manual force and repetition requirements associated with job duties.²³ Establishing such a background level of disease—i.e., the rate of disease expected in the general population with minimal or no exposure to the relevant risk factors—permits the determination of whether an elevation of the disease and its symptoms are, in fact, a consequence of risk factor exposure. D.I. 350 at 23–34, 36–43.

***21** Based on twenty studies²⁴ found in the open epidemiological literature, Punnett concluded in *Schneck* (as well as in the matter under consideration) that such:

literature provides reasonably convincing evidence that VDT work *per se*, whether measured in hours worked per week, years duration of employment, typing speed, or intensity of keying (data entry vs. interactive tasks), is causally related to an elevated risk of **musculoskeletal disorders** [and related **soft-tissue disorders**].^{25 26}
 D.I. 311, Ex. A–652.

In reaching her conclusion on the causation of keyboard induced injury, Punnett discussed eight criteria, including types of error and bias, commonly considered by epidemiologists in determining causality: (1) random misclassification of exposure or of health status; (2) selection bias; (3) information or recall bias; (4) confounding; (5) temporal sequence of cause and effect; (6) strength of association; (7) exposure-response relationships; and (8) biological plausibility and external validity. D.I. 311, Ex. A–632–37, Ex. A–652–54.

Rather than argue that the set of criteria employed by Punnett in reaching her conclusion is unsound, IBM submits that Punnett's opinions should be excluded because *none*

of the eleven “strongest” studies relied upon specifically discusses an association, much less a causal relationship, between CTS and video display terminal use. D.I. 309 at 19. Moreover, the following methodological flaws in the studies cited “render [Punnett's] opinions regarding causation unreliable and unhelpful to the trier of fact”: (1) the studies discuss subjective symptoms rather than disease entities; (2) the studies have poorly conceptualized objectives—i.e., ones that are unclear and not stated quantitatively; (3) all but one of the twenty studies are cross-sectional in design, thereby potentially limiting results to the identification of an exposure and an outcome, rather than a cause and effect relationship; (4) almost all of the cross-sectional studies are self-reported, and consequently susceptible to study subject misclassification and over-report “response bias”; (5) two of the top eleven studies have potential bias in subject selection, therefore limiting the studies' conclusions; (6) all of the eleven top studies fail to take into account the fact that “**musculoskeletal disorders**” are not unique to office and manufacturing workers; and (7) the studies do not account for other possible causes. D.I. 309 at 15–19.²⁷ Finally, defendant maintains that Punnett's literature review conclusions are vague and unsubstantiated, as evidenced by the doctor's own admission that no meta-analysis or calculation has been conducted, but yet she “estimates” that the “relative risk of shoulder, arm and hand disorders is at least two for the keyboard work of at least four hours per day....” D.I. 309 at 19, D.I. 311, Ex. A–652. As Punnett is unable to quantify the relative risk of use of keyboards versus the “risk” of any person within the general population getting a **musculoskeletal disorder**, it is impossible for a jury to conclude that the keyboard user's “risk” presents an unreasonable risk of harm or one so probable as to render the instrument as defective. D.I. 309 at 19–20. In light of these considerations, and where the epidemiologist fails to establish an association between the injuries allegedly suffered by plaintiffs and any amount of typing, it must be held that Punnett's conclusions are “unfounded and unreliable and ... completely unhelpful to the trier of fact.” D.I. 309 at 20.

***22** In support of this contention, defendant submits corroborating affidavit testimony by expert epidemiologist Dr. Dimitrious E. Trichopoulos (“Trichopoulos”).²⁸ Trichopoulos, a physician and epidemiologist, is currently the Chairman of the Department of Epidemiology at the Harvard School of Public Health, as well as the Director of the Center for Cancer Prevention at Harvard. More than one hundred of his professional publications focus

on occupational or environmental epidemiology. Aff. of Trichopoulos at ¶ 1.

In formulating his “assessment of the evidence concerning a possible link between keyboard operation and data entry tasks and [musculoskeletal disorders](#) in video display terminal-related work,” Trichopoulos reviewed Punnett's report, as well as the twenty studies upon which she based her conclusions. Aff. of Trichopoulos at ¶ 2–3. As a result, IBM's expert unequivocally disagrees with Punnett's conclusions, based on differences in both the basic premises²⁹ and the weighing and interpretation of the existing evidence. Specifically, Trichopoulos states the following criticisms, in addition to providing a brief critique of each individual study:

... It is essential to note that the [musculoskeletal disorders](#) under consideration in Dr. Punnett's report and the relevant studies do not concern disease entities or clinical syndromes as defined in the medical and epidemiological literature, but rather a collection of symptoms (subjective) and occasionally signs (objective). *I submit that the concerned scientists should focus on the understanding of the etiology of a scientifically defined disease entity, rather than on the attribution of symptoms that may represent physiological responses to extreme exposures of particular organs or systems in the process of particular occupational activities.* I have little difficulty accepting that any occupation involving intense use of any particular organ will be associated with symptomatology from that organ; the problem is whether symptomatology can develop into an independently defined and generally recognized (World Health Organization 1977) disease entity.

Aff. of Trichopoulos, Ex. A at 3–4.

No study has examined individuals with clearly defined disease or an a priori determined clinical syndrome (Morris 1975Morris 1975). Five of the studies (Bernard et al.1992, Hunting et al.1981, Kamwendo et al.1991b, Nathan et al.1988, Onishi et al.1982) have used some objective examination or measurement and these measurements were “negative” (indicating no association) in two studies (Bernard et al.1992, Nathan et al.1988), equivocal in two others (Hunting et al.1981, Kamwendo et al.1991b), and positive in only one (Onishi et al.1982).

Eighteen studies have used questionnaire-ascertained symptomatology as outcome variables and of these nine were reported as clearly or suggestively positive (Bernard et al.1992, Burt et al.1990, Duncan and Ferguson 1974,

Heyer et al.1990, Kamwendo et al.1991a, Maeda et al.1980, Rossignol et al.1987, Smith et al.1981, Stellman et al.1987) whereas in three studies (Hunting et al.1981, Kamwendo et al.1991b, Knave et al.1985) the results were equivocal and in six studies (Fahrbach and Chapman 1990, Hales et al.1992, Sauter et al.1991, Starr et al.1989, Starr et al.1985, Star 1984) the results were essentially “negative” (no association). *It appears that VDT work has not been shown to be causally associated with an a priori defined disease or clinical syndrome, and there is very little evidence for an association based on objective pathophysiologic measurements.* By contrast, studies based on questionnaire-ascertained symptoms are more often than not positive for an association between VDT related work and musculoskeletal symptomatology, although the results are by no means uniform across studies. When associations are reported they are usually weak, with odds ratios below 2 and squared partial correlation coefficients below 0.05. Indeed, these associations with VDT related work, are, as a rule, weaker than the corresponding associations with gender (e.g. Knave et al.1985) or variously operationalized psychosocial variables (eg. Burt et al.1990, Hales et al.1992).

**23 The existing evidence does not support a casual link between VDT related work and a clinically defined [musculoskeletal disease](#) or syndrome.* There is circumstantial evidence for an association between VDT related work and subjective musculoskeletal symptomatology, but it is difficult to establish whether, and to what extent, the latter association reflects a psychosocially modulated selection process.

Biomedical considerations and other paradigms indicating that excessive functioning can lead to adverse symptomatology suggest that VDT related work may indeed generate musculoskeletal symptoms, although there is no evidence that these symptoms are based on objectively ascertainable pathology or otherwise objectively defined clinical disease. The odds ratios linking VDT related work with musculoskeletal symptoms are generally below 2 and they are, as a rule, lower than those reflecting the influence of several demographic and psychosocial variables.

Aff. of Trichopoulos, Ex. A. at 11–13 (emphasis added) (internal citations omitted).

In a supplement to the previously cited report, Trichopoulos expands on his critique of the Punnett report, asserting, in relevant part:

... There is extensive literature on the methodology for quantitative summarization of study results frequently referred to as meta-analysis. Most researchers agree that meta-analysis plays a central role in the summarization of *randomized clinical trials*. The characteristics of clinical trials that make them amenable to meta-analysis are: (a) they refer to a disease; (b) they focus on an agreed explicit outcome as, for example, survival or metastasis-free time; (c) the randomization process allows control of both identifiable and elusive confounding factors since, within the constraints of chance, confounding factors are equally distributed among persons exposed and non-exposed to the treatment under evaluation; (d) selection forces are accommodated through randomization, complete follow-up and allowance for competing causes for the outcome under study (e.g. death); (e) information bias is accounted for through blinding of both study participants and investigators (double-blind, placebo-controlled studies).

By contrast, epidemiologist are divided on the utility of meta-analysis for *observational (non-experimental) investigations*: some consider it useless or even misleading, whereas others believe that it can provide an additional insight to what can be obtained from critical evaluation of individual studies. However, most epidemiologists would agree that meta-analysis is a blunt tool in observational (non-experimental) research, and can only be useful if it is based on the sound epidemiological studies that had similar designs, evaluated similar exposures, focused on similar outcomes, addressed similar sets of potential confounders and have excluded with reasonable confidence selection and information bias.

In this light, it is clearly unrealistic to attempt a proper meta-analysis of the studies that have examined the relation, if any, between keyboard operation and [musculoskeletal disorders](#).... The operational definition of exposure(s) varies by study, from meat-cutting, to cake decoration, to operating posture, to job dissatisfaction, to psychosocial work environment, to video display terminal work; the outcome varies from self-reported discomfort, to (unadjusted for age) median nerve sensory velocity, to (rarely) clinically indicated [carpal tunnel syndrome](#), to *ad hoc* defined conditions “[cumulative trauma disorder](#)” (notwithstanding the absence of evidence of trauma); confounding factors are inconsistently considered

and inadequately addressed; selective participation is frequently acknowledged but the resulting bias is rarely evaluated; scant attention is paid to the high likelihood for information bias; and different measures of alleged effect are used, depending on study circumstances and expertise of the investigators (prevalence ratio, odds ratio, incidence ratio, difference of mean values, etc.).

*24 Aff. of Trichopoulos, Ex. C. at 1–2.

It is generally acknowledged that establishment of causation hinges either (1) on experimental evidence from humans or an appropriate animal model (neither of which is at present available for the issue under consideration) or (2) more frequently, on observational human evidence ascertained through epidemiological studies. In strict terms, none of the 20 studies reviewed by Dr. Punnett in her 1993 report is a bona fide epidemiologic investigation, and none has been reported in a peer-reviewed epidemiologic journal (books, reports, and conference proceedings are not considered as peer-reviewed publications). This does *not* indicate that these studies are of no value: they do highlight ergonomic issues and relevant psychosocial factors and they may even help to identify the exposure and outcome parameters that deserve proper epidemiologic scrutiny in subsequent investigations. Only the three recent papers by Bergqvist can be considered as epidemiological and their results do not provide support for an overall association between video display terminal work and musculoskeletal problems.

In rare occasions, associations are so strong that causality may be established even when the data were generated from imperfect studies. However, when a causal link is absent, weak, or questionable the empirical evidence should be based on demonstrably valid studies and should be supported by convincing biological arguments. With respect to the alleged link between keyboard operation and [musculoskeletal disorders](#) none of these conditions is met. Meta-analysis can summarize valid data but it is not a remedy for data of poor or questionable validity.

The attempts of Dr. Laura Punnett to derive summary quantitative estimates from the studies she has reviewed are grossly inadequate and, in fact, misleading. This does *not* imply that Dr. Punnett lacks the necessary expertise to undertake a meta-analysis; on the contrary, I believe that Dr. Punnett is a qualified and competent colleague. However, the studies on VDT work and [musculoskeletal disorders](#) are so diverse in design, have so limited control

on information bias, focus on so different outcomes and use so different effect estimators that no methodology can abstract a reasonably meaningful conclusion for the issue under investigation. The only statement that can be made is that studies that have stronger methodological safeguards and use more objective outcome measurements tend to show no association between VDT work and [musculoskeletal disease](#) in the upper extremities- and *vice versa*.

Aff. of Trichopoulos, Ex. C at 6–7 (emphasis in original).

In response to these criticisms, plaintiffs have provided the affidavit of Dr. Stephan Zoloth (D.I.327, Ex. 40), a professor of Epidemiology and Public Health at Hunter College in New York, as well as the Director of Hunter College Center for Occupational and Environmental Health.³⁰ D.I. 327, Ex. 40 at ¶ 1. This affidavit originally was submitted in the *Schneck* case and is now proposed for the same purpose.

***25** As part of his professional activities, Zoloth acts as a peer reviewer for the American Journal of Public Health and the American Journal of Industrial Medicine, customarily reviewing articles submitted to these periodicals for publication. *Id.* at ¶ 2. According to his affidavit, Zoloth is familiar with Punnett's Report at issue, as well as the literature reviewed by Punnett therein. *Id.* at 3. Regarding IBM's criticisms of Punnett (in particular, the studies relied upon by her), Zoloth provides the following comments:

16. *Quality of the Studies*

First, it is important to note that Dr. Punnett's review is not restricted to just the 20 VDT studies. Indeed, the non-VDT studies which discuss the established economic risk factors (force, repetition, awkward posture, ...) which are also present in keyboard use, are important to consider. However, even focusing on just the VDT studies, it is clear that they are all either peer reviewed or government issued, and are all authored by reputable scientists. As such they are of sufficient quality to allow for Dr. Punnett's evaluation.

17. *Symptoms Reported*

To the extent that the researchers in the cited studies discussed symptoms reported by the subject populations, this is a proper and common feature of such occupational health studies. Of course, in the methods sections of various of the reports, the researchers discuss the symptom

complexes being studied and how they relate to defined injuries and disorders.³¹ Accordingly, they do not present an obstacle to Dr. Punnett's evaluation. Rather, the studies' authors are assessing different symptomatology to determine the prevalence of work-related [musculoskeletal disorders](#)³² in the various populations. Again, this is entirely proper. Moreover, while symptomatology may be viewed as a surrogate for disease, it can also be seen as a precursor. This makes its consideration entirely proper.

18. *Statistical Association v. Causation*

Within any particular study on any subject (within the field of epidemiology) the association of exposure and outcome is properly noted by the researcher. It is, however, within the larger scope of a comprehensive review—such as that performed by Dr. Punnett—that findings of causation are properly discussed. The tests for such conclusions are the well-established epidemiological criteria set out in the beginning of Dr. Punnett's report (pp. 4–10). Since she has followed these criteria, it is entirely proper for her—especially given (sic) her qualifications and experience—to draw conclusions based upon such a review. Indeed, the studies, being of sufficient quality, properly lend themselves to such findings. While IBM's lawyers may review the studies and (assuming they follow the proper criteria) come to different conclusions, that does not mean that the studies do not support Dr. Punnett's conclusions. In fact, they do.

19. *Dr. Punnett Acknowledges the Limitation of the Studies in Her Review*

***26** Any good and credible epidemiologist will be the first to admit that no study or review is perfect. In fact, it is expected of epidemiologists that they will fully and forthrightly address the weaknesses in their work. Dr. Punnett has properly done this. This in no way impairs her credibility. In fact, just the opposite is true. Moreover, it does not detract from the reliability of her work. Such acknowledgment simply puts into proper context the scope of the work and its limitations. None of those (properly) discussed by Dr. Punnett invalidate or weaken her conclusions.

20. *Cross–Sectional Design*

Cross-sectional studies are valid and generally accepted study designs in epidemiology and are properly considered in a review such as Dr. Punnett's. It is true that a *potential* limitation inherent in such a design is the subject of temporal relationship between exposure and outcome, if not properly considered and controlled for. The authors of the subject studies acknowledge this, as does Dr. Punnett, who adequately deals with this subject in the body of her report as well as in Table 1. Accordingly, it does not impair the ability to find a causal relationship in this context.

21. *Self-Reporting*

Use of questionnaires to elicit information concerning the outcome variable in an occupational epidemiological study is standard and well accepted in the field. While IBM's lawyers point to the potential for over-reporting, there is just as great a likelihood of under-reporting, as active workers may choose not to report outcomes for fear of jeopardizing their employment. Moreover, and on a related note, one should consider that the "healthy worker effect" (sick/injured workers are selectively removed from the studies population) will mask the true effect of the exposure.

22. *Bias*

As noted above, no study is perfect or without any potential bias or confounding. IBM's lawyers point to Dr. Punnett's observation that two of the twenty VDT studys [sic] contain potential selection bias, and are critical of her using those studies as part of the bases for her conclusions. This criticism is not well founded. Firstly, as Dr. Punnett properly points out, selection bias can affect results in either direction. Moreover, there is no indication in these two studies whether this bias is active and to what extent. However, in all events, it would be improper to disregard the findings of these studies as advocated by IBM's lawyers. Rather, Dr. Punnett properly considers them—acknowledging their potential limitations—in viewing the whole picture presented by the entire literature.

23. *Confounding*

Again, no study is perfect or completely free of possible confounding. While many of the VDT studies control for some confounding factors some do not. Methodologically, this is properly noted and dealt with by Dr. Punnett in her report and in Table 2. Having done so, it is up to the reviewer to form a professional judgment as to whether or not the potential confounding precludes the drawing of conclusions. Dr. Punnett has done this. While IBM's lawyers may disagree with this conclusion, there is no reasoned basis to disregard Dr. Punnett's judgment.

*27 D.I. 327, Ex. 40 at 5–9.

Punnett further defends the aforementioned studies and her conclusions in a supplemental report dated July 31, 1995. D.I. 327, Ex. 42. Addressing those criticisms set forth by Trichopoulos, Punnett counters that IBM's epidemiologist area of expertise lies primarily in the study of *cancer*, a disease whose diagnosis, progression and treatment naturally lend themselves to a very different kind of epidemiological study than that associated with *musculoskeletal disorders*. To wit, as a consequence of the steady worsening of health of a patient afflicted with *cancer*, that patient is extremely likely to seek medical care, be diagnosed by objective medical tests, be recorded in *cancer* registries and ultimately have *cancer* listed as the cause or underlying cause of death on a death certificate. Thus, administrative databases are generally available to retrospectively and prospectively ascertain *cancer* cases and potentially link them to other databases offering information on various possible exposure types. In contrast, individuals suffering from *musculoskeletal disorders* "may or may not seek treatment at any particular point in the progression of the condition; they may experience prolonged periods of pain and impairment or alternating periods of recovery and recurrence (with or without treatment); and there are no uniform case reporting mechanisms at either the state or federal level in this or most other countries." D.I. 327, Ex. 42 Supp. Report at 1–3. Moreover, unlike with *cancer*, *musculoskeletal disorders* may enter "remission" in patients with reduced exposure to the stressors, such as resulting from ergonomic intervention in the workplace, with the added benefit of the prevention of future disorders. *Id.*

Under these circumstances, where routine databases are not available for case ascertainment of *musculoskeletal disorders*, epidemiologists generally rely upon alternative approaches for the identification of affected individuals, such as self-reported symptoms. According to Punnett,

cases defined by symptoms alone and those defined by findings on physical examination show extremely similar associations with the force and repetition characteristics of subjects' jobs (Silverstein 1986, 1987) ... [T]here is a strong correlation between the frequency of symptoms, for example, among a group of occupations, and the frequency of workers' compensation claims, and of work-related repetitive trauma disorders recorded by employers in those same occupations (eg., Fine 1986). Standardized questionnaire items have been proposed (eg., Kuorinka 1987, Levine 1993) and evaluated with respect to their validity, reproducibility and sensitivity to change; the international comparability of case definitions is increasing.

D.I. 327, Ex. 42 Supp. Report at 3.

In further response to Trichopoulos' criticism that an outcome definition is inherently vague and weak when derived from questionnaires, the epidemiologist also notes that the use of questionnaire items to determine case status is not unique to [musculoskeletal disorder](#) study; standardized questionnaires for the assessment of [chronic pulmonary obstructive disease](#) have been widely used by epidemiologists for a number of years. *Id.* at 3–4.

*28 Punnett's Supplemental Report and recent *in limine* testimony also specifically address and refute Trichopoulos' assertions that: (1) the studies upon which she relied were not peer-reviewed; (2) there is insufficient experimental evidence that [musculoskeletal disorders](#) may develop as a consequence of repetitive motion, static muscle loading and/or awkward postures; (3) the potential for information bias is much greater in studies where exposure measures were derived from questionnaire data and (4) those studies where there were multiple ergonomic exposure dimensions to the risk of [musculoskeletal disorders](#) poorly or vaguely assessed those potentially confounding individual exposures. *Id.* at 4–6.

With regard to the issue of peer review, Punnett testified at her *in limine* hearing that there are several different types of accepted peer review, which in and of itself is a “fluid” concept. There is “formal” peer review, where an article submitted to a scientific journal is distributed to “outside” reviewers (other than the journal's editor and unknown author) for comments. Another form of peer review consists of presentation of a study at a scientific conference or symposium, where it is subjected first to an abstract critique for sound methodology and subject matter relevance by the particular conference's organizers, then later critiqued and commented upon by the conference's audience. Yet another form of peer review consists of review and comments on an article by the editor of the journal to which the work is submitted. D.I. 350 at 56–58.

According to Punnett, of the twenty studies upon which she relied, all were peer-reviewed papers, with the exception of the three NIOSH health hazard evaluation reports, two of which have subsequently been published in peer review journals. However, Punnett maintains that NIOSH reports actually undergo both an internal and (often) external peer review process prior to publication in their present state, so the NIOSH articles considered were also subject to the appropriate review. Further, in reference to her own report prepared for this litigation, Punnett notes that it was presented at a medical conference sponsored by the National Institute of Arthritis and Musculoskeletal Disease in conjunction with several other professional associations, and was reviewed by one of the editors who compiled the conference proceedings for publication. Moreover, it is currently under formal peer review for publication in an unidentified scientific journal. D.I. 350 at 90–92.

As for Trichopoulos' concerns that no study cited had examined individuals with clearly defined disease or an *a priori* determined clinical syndrome, Punnett replies:

It may be true that in some studies these case definitions are based on symptoms “that are difficult to combine into a single disease from the point of view of clinical medicine.” However, it is also the opinion of numerous physicians that clinical medicine does not yet provide the necessary diagnostic techniques for these conditions, especially in their early stages, or offer the appropriate taxonomy. The argument that an epidemiologist should only study clinically defined diseases begs precisely the contribution that epidemiology can make to the development of an appropriate clinical case definition and

seems dated in light of many recent developments in the field. For example, epidemiologists were involved early in the scientific attempts to understand the immune system disturbance that is now characterized as [Acquired Immune Deficiency Syndrome](#), but which was under study long before the disease mechanism was understood or a case definition had been standardized (utilizing epidemiologic data). Many epidemiologic studies utilize as their outcomes not clinically diagnosed disease but markers for early stages in pathogenesis ... precisely because they offer a greater possibility of identifying affected individuals before clinical disease has developed and when secondary prevention will likely be more effective.

*29 D.I. 327, Ex. 42 Supp. Report at 4 (citations omitted).

Thus, in summary, Punnett concludes:

... there is epidemiologic evidence not only that “excessive functioning ...” (and specifically) “VDT related work may indeed generate musculoskeletal symptoms.” (Ex. A, p. 13). There is also evidence that VDT usage is associated with disorders that produce findings on physical examination and clinical testing. Furthermore, there is evidence that musculoskeletal symptoms are valid and reproducible and serve as markers for medical care utilization and other endpoints, whether or not the pathology has been defined or can be objectively assessed as of yet with available clinical techniques. To my knowledge, there are no data showing the plausibility of alternative explanations for the associations between VDT use and [upper extremity disorders](#). In the light of laboratory studies demonstrating several biologically plausible pathomechanisms, the epidemiologic evidence is most credibly interpreted as causal.

D.I. 327, Ex. 42 Supp. Report at 6.

In light of defendant's criticisms and plaintiffs' responses, the issue regarding the admissibility of Punnett's expert testimony is quite clear: the Court must determine whether Dr. Punnett had good grounds to rely on the studies in question to draw the conclusion that VDT use causes [musculoskeletal disorders](#).

See [Paoli II](#), 35 F.3d at 749; See also [DeLuca v. Merrell Dow Pharmaceuticals, Inc.](#), 911 F.2d 941, 953 (3rd Cir.1990) (“Rule 703 is satisfied once there is a showing that an expert's testimony is based on the type of data a reasonable expert in the field would use in rendering an opinion on the subject at issue.”).

The Third Circuit has stated that “it is the judge who makes the determination of reasonable reliance, and that for the judge to make the factual determination under [Rule 104\(a\)](#) that an expert is basing his or her opinion on a type of data reasonably relied upon by experts, the judge must conduct an independent evaluation into reasonableness.” [Id.](#) at 748. Of course, “the judge can ... take into account the particular expert's opinion that experts reasonably rely on that type data, as well as the opinions of other experts as to its reliability, but the judge can also take into account other factors he or she deems relevant.” *Id.*

While the parties have presented undeniably conflicting testimony regarding Punnett's examined studies and her resulting conclusions, the Court finds that the studies relied upon by Punnett are of the type reasonably relied on by experts in the field to render a conclusion with respect to general causation. Although none of the underlying studies actually concludes that VDT use causes [musculoskeletal disorders](#), it is also recognized that “epidemiology cannot prove causation; causation is a judgment issue for epidemiologists and others interpreting the epidemiological data.” *Schneck Op.* at 31, quoting the *Federal Judicial Center, Reference Manual on Scientific Evidence* 157 (1994); see *Id.* at 126 (“Association is not causation A strong association that is demonstrated consistently in a series of research projects leads a researcher to infer that a causal relationship exists. Even the best of studies do not demonstrate more than a high probability of causal relationship between exposure to an agent and a disease.”); see also [Diaz v. Johnson Matthey, Inc.](#), 893 F.Supp. 358, 375 (D.N.J.1995) (citations omitted) (“A cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists.... If conclusive evidence were necessary to admit ... [a] theory on general causation, we might as well be proceeding under the *Frye* general acceptance test rejected by *Daubert*. ”). As noted in *Schneck*, Zoloth strongly approved of Punnett's conclusion on general causation in light of her proper reliance upon underlying studies which were both reliable and of the type that an expert would reasonably rely on to establish causation. D.I. 327, Ex. 40 at ¶ 18. While IBM's expert, Trichopoulos, disputes these conclusions, this Court finds sufficient evidence to hold that Punnett had “good grounds” to rely on these studies to reach her conclusion, and that Trichopoulos' contrary testimony is more properly reserved for consideration by a jury as to the issue of weight. Consequently, it is recommended that

defendant's motion to exclude Punnett's general causation testimony be denied.

*30 As part of its argument, defendant contends that since Dr. Punnett does not relate the injuries allegedly suffered by plaintiffs to any amount of typing or keyboard use, her opinion testimony “does not fit the allegations of the plaintiffs in this case, and is, therefore, completely unhelpful to the trier of fact,” relying on *Daubert* at 2795–96. The *Daubert* analysis under the “fit” or helpfulness requirement of Rule 702 necessitates “a valid scientific connection to the pertinent inquiry as a prerequisite for admissibility.” *Id.* (emphasis added). As noted by *Daubert*, “[F]it is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes.” *Id.* However, Punnett's general causation opinion is not being propounded in the abstract and is not the only opinion on causation. Although Punnett is not being called upon to testify about a relationship between plaintiffs' alleged injuries and their keyboard use or the IBM keyboards involved, as will be addressed further herein, Dr. Bleeker specifically relies upon Dr. Punnett's methodology and analysis in formulating her general causation opinion and applies that to the injuries involved in this matter. Therefore, defendant has failed to demonstrate that Punnett's testimony will not “assist the trier of fact to understand the evidence or to determine a fact in issue.” Fed.R.Evid. 702.

C. Dr. Margit Bleeker

Margit Bleeker (“Bleeker”), M.D., is a board-certified psychiatrist and neurologist who serves as the Director of the Center for Occupational and Environmental Neurology in Baltimore, Maryland and as a consulting neurologist to the Hopkins Health System. D.I. 310, Curriculum Vitae, p. 2. She is also a medical/ergonomic consultant at the Washington Post, for which she reviews workstations and evaluates employees who are developing repetitive strain injuries. D.I. 310, Ex. A–5 at 20–21. Plaintiffs proffer the opinions of Bleeker on the issue of medical causation generally, and specifically with respect to plaintiffs' individual claims of *carpal tunnel syndrome* resulting from use of keyboards.³³ D.I. 310, Ex. A–3 at 8–9.

With regard to the issue of general medical causation, Bleeker opines that “*carpal tunnel syndrome, as far as I'm concerned, is a keyboard issue* and I include with the keyboard—I include, for instance, the height of a keyboard tray even though somebody might say that's the workstation.

That is where the keyboard is being used and that is part of the keyboard problem. I mean, the height of the monitor, whether that's inappropriate, has nothing to do with *carpal tunnel syndrome*.” D.I. 310, Ex. A–73 at 299 (emphasis added). Bleeker's summary statement proffered herein followed detailed deposition responses regarding keyboard design and use (specifically, typing technique, position, posture, intensity, duration and key depression force) and their association with such repetitive strain injuries as CTS.³⁴ D.I. 310, Ex. A–69–71 at 276–286, A–73 at 291–296. During her recent *in limine* testimony in this matter, Bleeker maintained that consistent keyboard use may cause *carpal tunnel syndrome*. (See Bleeker *In Limine* Hearing Testimony, Nov. 3, 1996 and Dec. 6, 1996, D.I. 363 and 353 respectively).

*31 As to the issue of specific causation, in a January 5, 1996 occupational neurology evaluation of Allen, Bleeker records that “Ms. Allen is a 32-year-old right-handed female who was originally evaluated on November 3, 1994, for continuing problems in both of her hands following *carpal tunnel release* bilaterally. At that evaluation, the history and physical examination were suggestive of *carpal tunnel syndrome* bilaterally.” D.I. 310, Ex. A–111. As stated as her “Impression” during the November 1994 examination, the doctor again concludes that “[t]he history demonstrated a strong temporal association between the onset of symptoms and increased keyboard use.” D.I. 310, Ex. A–111. While Bleeker's November 3, 1994 and January 5, 1996 occupational neurology evaluations of plaintiff Bowers do not explicitly cite keyboard use as the cause of her *carpal tunnel syndrome*, both reports focus on Bowers' keyboard activities and its alluded direct association with her CTS injury and its recurrence. D.I. 310, Ex. A–113–17. Moreover, in her deposition testimony, Bleeker unequivocally claims keyboard use as the cause of both plaintiffs' medical problems:

Q: Is it your opinion that Mrs. Allen's and Mrs. Bowers' *carpal tunnel syndromes* were caused solely by their use of computer keyboards?

A: What you have to realize is that when you are formulating that opinion is that you look at the fact that these individuals—I could not find any other stressor except a change in what had gone on in their work place or the fact that they were using their keyboard in, maybe, a poorly designed work place and they weren't using the keyboard correctly. That caused the problem.

D.I. 310, Ex. A–73 at 298.

During her *in limine* hearing in November and December 1996, Bleeker was equally emphatic that plaintiffs' respective CTS problems were a result of computer keyboard use, rather than of their routine activities and hobbies, although she later conceded that the activities of daily living (ADLs) and other modifiers (i.e., body weight, birth control pills) could exacerbate the CTS conditions:

Q: The question basically was, did you come to a determination of causality [of CTS] through these examinations of her [Ms. Bowers'] problems?

A: Yeah. I think it's—by causality, I'm more interested in *when the problem began, and what was going on at that point*. And I feel that it was due to using the keyboard. And, unfortunately, in this case, it looks like it was exacerbated because the keyboard, by the patient's description *when she was demonstrating how she was using it, was clearly too high*.

D.I. 363 at 25.

Q: Do you state anywhere, in your impression, that the etiology of Ms. Bowers' diagnosed bilateral carpal tunnel syndrome is due to the keyboard or any aspect of the keyboard?

A: I think if you read the entire impression, what I am trying to do is to demonstrate that, for instance, when her condition was treated, the bilateral carpal tunnel syndrome was treated with surgery, symptoms improved. She had successful surgical outcome. And then, when she returned back to work, the symptoms again increased in severity.

*32 I make statements like that because, again, it is having the relationship between the development of the symptoms with the use of the keyboard which is helping us to establish causality.

I tried to explain what was going on with the elevated keyboard, and indicating that she was typing in a position that where she could have increased pressure inside the carpal canal. Again, a causal relationship between increased pressure in the carpal canal, we know that from the literature, that people with carpal tunnel syndrome have increased pressure within the carpal canal, and that is clearly a risk factor for the development of carpal tunnel syndrome. So, yes, as far as I am concerned, there

is not a question that the use of the keyboard was causally associated with the development of the carpal tunnel syndrome.

D.I. 353 at 12–13.

Q: What sort of non-work activities did you note in Ms. Bowers' history that could be possible causes of carpal tunnel syndrome?

A: I think that you need to realize that there are many contributing factors to the development of carpal tunnel syndrome. Could her employment at the Acme, where she is grabbing parcels and putting them through the scanner, could that have added a little notch. Obviously, it could. But the fact is that you need to look at the number of hours. It's just the same explanation that is given, oh, it's the crocheting, it is the knitting, it is washing the clothes at home. You are not doing that for 37 and a half hours a week. You can actually do a little bit and stop. That is very different than with many of these jobs on the keyboard.

D.I. 353 at 22.

Q: You did not say or conclude in this report, did you, that keyboard use caused her [Ms. Allen's] carpal tunnel syndrome.

A: Well, I guess I said it in my way. If by saying there a strong temporal association between onset of symptoms and a dramatic increase in her keyboard use, to me, that says that one caused the other.

Q: Is that enough, Doctor, just having a temporal association between two things, is that enough to assume causation?

A: Clinically? Sure.

Q: From a scientific and medical perspective, doesn't causation require more than just a temporal relationship between the suspected cause and the suspected effect?

A: No. I mean, its very much—if somebody is throwing a baseball and develops shoulder pain, are they able to associate throwing the baseball with the onset of the shoulder pain? I mean, I don't think too many people would question that. And that's the same thing we're talking about here.

Q: How about in an area of controversy; that is, where it's controversial in the scientific and medical arena as to whether a given cause produces a given effect. In that situation, is a temporal relationship alone sufficient to premise or basis an opinion of causation between the two items?

A: You know, what it is, is I don't know if I fully agree with—we have been discussing causation of [carpal tunnel syndrome](#) with keyboard use. You have brought up that it's a multifactorial problem. No one is going to deny that it's multifactorial. One of the major factors happens to be ergonomic stressor from the keyboard. If you want to bring in, you know, other modifiers, such as her weight, whether she's on birth control pills, other things like that, those are modifiers.

*33 D.I. 353 at 122–23.

Q: Is it your impression that her [Ms. Allen's] use of the switchboard [versus the computer keyboard] and her activities of daily living were the cause of her symptoms?

A: Absolutely not.

D.I. 353 at 130.

During her *in limine* testimony on November 23, 1996, Dr. Bleeker described the typical methodology applied in making a diagnosis of an illness, and whether there is a causal factor associated with the patient's particular occupation:

Basically, one approaches as one approaches any patient with reviewing any medical records that have been provided by the individual or their [sic] physician. One gets a history. And part of that history is specialized, because part of it is an occupational history, where one is going through the various jobs and positions that the person has been in, and what those positions have actually entailed.

And one also obviously goes through the medical history; meaning, what other medical conditions have they been diagnosed with. Do they have any other sort of general symptoms that might suggest that there's an underlying condition that hasn't been diagnosed that needs to be—that needs to be looked at.

And then one does a physical examination. If it's indicated, [nerve conduction studies](#) are performed. In some cases, we

actually even do MRIs [[magnetic resonance imaging](#)] as part of our workup, because we may be seeing somebody after surgery who is having problems.

Again, there are different avenues that one may take in the evaluation. And as part of this history taking and examination, one is trying to exclude other etiologies. So one is looking at hobbies and other ergonomic stressors to the upper extremities.

And one is always being very careful to try and determine the temporal association between what happened in the workplace and the onset of the symptoms. And what actually went on with relieving the symptoms, if they were treated by another physician, you know, what was modified.

D.I. 363 at 8–10.

Bleeker further opined that when examining the impact of nonwork activities on the development of CTS, one typically considers the intensity and duration of each nonwork activity. When questioned about the basis for her temporal association between CTS and keyboard use (i.e., additional reliance on literature on occupational problems or primary emphasis on her own clinical experience), Bleeker responded:

The thing is that one obviously keeps abreast of the literature. I mean, I have a library with many journals, which one can see which ones we have been subscribing to.

So one is—[carpal tunnel](#) has been something that's been of interest to me, since I started in the early 80s. So it is something that whatever journal I'm looking at, and if it has a [carpal tunnel](#) article, it's always pulled and put into my files.

So one is relating to a body of literature that has been relating ergonomic stressors and these various health outcomes. I certainly can't necessarily point to one paper and say, this was “the article,” because it's basically many articles which have shown similar outcomes that I'm not [sic] relying on.

*34 D.I. 363 at 10–11.

Bleeker further commented on Punnett's work which reviewed health outcomes related to keyboard use,³⁵ stating that where CTS is a frequent outcome in the papers, there

is a demonstrated consistency between exposure and such outcome which may be used to establish causality.

With regard to the issue of general causation, defendant IBM's primary argument is that Bleeker's conclusion of a causative relationship between the use of keyboards and the development of such [musculoskeletal injuries](#) (i.e., [carpal tunnel syndrome](#)) as those suffered by plaintiffs is unsupported by recognized, scientifically verifiable studies. Moreover, assuming that legitimate scientific studies relate CTS to typing, there remain many other factors contributing to and causing CTS. D.I. 309 at 20–22, D.I. 334 at 13–14.

(a) General Causation

(1) *Daubert/Paoli II Factors*

(i) *Does the Methodology Consist of a Testable Hypothesis?*

Defendant does not contend that Dr. Bleeker's hypothesis—that repeated keyboard use is a substantial factor in the development of a cumulative [musculoskeletal disorder](#) such as [carpal tunnel syndrome](#), and that such a disorder can be prevented and treated with early identification and ergonomic work modifications—is not testable. Accordingly, this factor will weigh in favor of the admissibility of the proffered testimony.

(ii) *Has the Methodology Been Subject to Peer Review?*

During her recent *in limine* testimony Dr. Bleeker specifically referred to the review of epidemiologic studies relating health outcomes (such as CTS) to reported keyboard use presented by Dr. Laura Punnett and previously described and considered at length by this Court. Bleeker cited Punnett's Report, among other more broad references to available scientific literature, as a basis for her general causation opinion proffered in this litigation.³⁶ D.I. 363 at 48–50. This Court has already determined that Punnett had good grounds for relying on the studies she used in formulating her general causation conclusion, and that the conflicting opinions of the respective parties' outside experts on the reliability of such studies is appropriately left to the jury to weigh.

With regard to issue of specific causation, according to the Journal of American Medical Association (“JAMA”) report of Dr. David Rempel (“Rempel”), a well-regarded expert, the following mainstream methodology is appropriate for application to ascribe the cause of occupationally-related upper extremity [cumulative trauma disorders](#): (1) make a reasonably specific and accurate diagnosis; (2) exclude

nonoccupational explanations for the disorder; (3) determine whether the disorder is plausibly associated with work-related risk factors, based upon the patient's work history; (4) interview the patient to find out whether the risk factors are present in sufficient degree; and (5) determine whether a temporal association exists between the work place risk factors and the onset or aggravation. D.I. 329, Ex. 54 at 839.

*35 Applying Rempel's outlined methodology, Dr. Bleeker conducted physical examinations of the plaintiffs, took their occupational, social and medical histories,³⁷ reviewed their medical records and conducted the conventional clinical tests and measures appropriate to the diagnosis (such as Phalen's, Finkelstein, Tinell's, [nerve conduction studies](#) and MRI of the affected extremities). Upon evaluation of the aforementioned factors, including the reasoned exclusion of nonoccupational factors—“potential confounders” or factors other than keyboard use which may have contributed to plaintiffs' CTS—Bleeker opined that plaintiffs' occupational use of keyboard equipment “was the cause of the development of [their] [carpal tunnel syndrome](#).” D.I. 311, Ex. A at 65. While the Court acknowledges that Dr. Bleeker did not account for every single possible potential confounder, it nonetheless recognizes the reliability of her conclusions.

In sum, this Court finds that the respective methodologies in question for general and specific causation have been subject to peer review and this consideration favors the admission of the proffered testimony.

(iii) *Is There a Known or Potential Rate of Error?*

The rate of error in Dr. Bleeker's methodology is directly related to the rate of error of those studies upon which her general causation conclusion rests—i.e., such as the reported results of Dr. Laura Punnett's review of the relevant literature on health outcome and keyboard use. With respect to Dr. Bleeker's consideration of Dr. Punnett's Report, as well as the studies relied upon by Dr. Punnett, this Court has already determined that there were good grounds for relying on such works. Ergo, the rate of error in these studies cannot be so significant thereby rendering invalid a conclusion with respect to general causation. However, the known or potential rate of error with respect to any of the other studies to which Dr. Bleeker broadly referred and relied upon in reaching her conclusion has not been posited. As such, this factor balances only slightly in favor of the admission of the proffered testimony.

(iv) *Were There Standards Controlling the Technique's Operation?*

Dr. Bleeker's underlying methodology regarding general causation relies substantially upon that utilized in Dr. Punnett's Report. And as previously noted, the Court has already determined that there were good grounds for relying upon the Report and the validity of the studies contained therein. As such, this component will weigh in favor of the proffered testimony.

(v) *Is the Methodology Generally Accepted?*

As the Court has noted in its analysis of previous factors, Dr. Bleeker's methodology applied in reaching her conclusion is substantially dependent upon the validity of that of Dr. Punnett's utilized in reaching her Report results, for each individual factor of the *Daubert/Paoli II* analysis. And as under the other factors, the Court holds that the methodology at issue is a standard and generally accepted epidemiological methodology. Thus, this element favors the admission of the proffered testimony.

(vi) *Is There a Relationship Between the Technique and Other Methods Established to be Reliable?*

***36** The Court's previous comments address this factor. While a broader base of literature and a more defined, delineated methodology with regard to general causation would have been preferred, Bleeker's primary reliance on Punnett's Report nonetheless supports that the doctor's methodology closely resembles established and reliable methods. Accordingly, this factor will weigh in favor of the admission of her testimony.

(vii) *Are the Qualifications of the Expert Based Upon the Methodology Appropriate?*

Defendant does not challenge Dr. Bleeker's qualifications for proffering a general causation opinion. With regard to specific causation, however, defendant points out that Bleeker is not a medical expert on hand disorders. While this may indeed be true, the Court is persuaded that Bleeker's medical training and extensive experience in the medical area now in issue render her qualified to speak on the matter of specific causation in this case. This factor therefore weighs in favor of the admissibility of the proffered testimony.

(viii) *Non-Judicial Uses*

The Court's prior criticism that Dr. Bleeker was a certain degree vague with regard to specifically identifying the scientific literature upon which she based her general causation conclusion, with the marked exception of Dr. Punnett's study, still stands. However, there is no doubt that the methodology utilized by Dr. Punnett, and adopted by Dr. Bleeker, has been used on a regular basis in non-judicial settings within the field of epidemiology. The same routine use certainly holds true with regard to the methodology applied by Dr. Bleeker in her specific causation determination. Thus, this factor will also weigh in favor of the proffered testimony.



(x) *Conclusion*

Upon consideration of the aforementioned factors, this Court finds that the *Daubert/Paoli II* analysis weighs in favor of admitting Dr. Bleeker's proffered testimony on general causation.

(2) *Fit*

Fed.R.Evid. 702's third requirement—that the evidence is relevant or “fits” under the facts of the case—also must be satisfied before an expert's proffered testimony may meet the *Daubert* test.

In the case at bar, Dr. Bleeker's testimony has been offered for the proposition that repeated keyboard use can cause such **musculoskeletal disorders** as **carpal tunnel syndrome**. In support of this assertion, Bleeker relies substantially upon the Punnett Report of epidemiological studies on this subject matter. Accordingly, this Court finds that Bleeker's testimony regarding general causation is admissible, where there is a “connection between the scientific research or test result to be presented, and particular disputed factual issues in this case.”

 *Velasquez*, 64 F.3d at 850 (quoting  *Downing*, 753 F.2d at 1237).

(3) *Conclusion*

Based on the foregoing analysis, the Court recommends that Dr. Bleeker's testimony on general causation be admitted.

(b) *Specific Causation*

***37** With regard to the issue of specific causation, IBM states that Bleeker's opinion that plaintiffs must have developed CTS from typing because of the “temporal” relationship between the use of keyboards and the

development of such injuries derived from the history given by plaintiffs themselves—is neither supported by the facts of this case nor by recognized scientific studies. D.I. 334 at 14. In particular, defendant asserts the following criticisms regarding Bleeker's qualifications and the formation of her causation conclusions: (1) Bleeker's explanation of the relationship of the physiology of plaintiffs' CTS to the use of a computer keyboard and why CTS must have been caused by plaintiffs' typing is not credible, where she is unable to cite to one scientifically verifiable study which supports her conclusions, nor can she state that her proffered explanation applies in fact to plaintiffs; (2) further, Bleeker is not a hand surgeon, and contradictory reports by plaintiffs' own hand surgeons, Drs. Boulos and Raisis, indicate that (i) no studies (to Raisis' knowledge) relate CTS to typing, (ii) there are many other factors which contribute to and cause CTS, including “activities of daily living,” and (iii) even if typing is one of the causes of CTS, the amount of typing and posture at a keyboard would not correlate directly to the development of CTS; (3) the doctor never questioned the plaintiffs about their typing technique or examined the particular keyboards or workstations used by plaintiffs, nor does she now specifically address the IBM keyboards at issue; (4) Bleeker is able only to opine that there is a “temporal” relationship between plaintiffs' typing and their development of CTS, a degree of association which even plaintiffs' expert epidemiologist Punnett recognizes is insufficient to conclude the existence of a cause and effect relationship; and (5) Bleeker is unable to satisfactorily explain why plaintiffs continue to suffer from CTS symptoms even after CTS release surgery and the discontinuation or curtailment of their typing, eventually conceding that “activities of daily living” could be responsible for Bowers and Allen's current symptoms. D.I. 309 at 20–22, D.I. 334 at 13–14.

Defendant further argues that Bleeker's methodology is unreliable where her conclusions are based upon incomplete case histories of the plaintiffs. To wit, Bleeker was unaware that: (1) Allen had been in an automobile accident and had fallen and [sprained her wrist](#); (2) Bowers also was involved in a car accident;³⁸ and (3) Bowers worked on other cash registers at Strawbridge's and J.C. Penneys, and, significantly, was using a cash register of unknown origin at Acme at the same time she was working on IBM machines. D.I. 334 at 14.

Plaintiffs maintain that Bleeker is eminently qualified to render expert testimony regarding specific causation and applied a reliable, medically-accepted methodology in her conduct of that analysis. D.I. 322 at 25–29.

Specifically, Bleeker conducted physical examinations of the plaintiffs, took their occupational, social and medical histories,³⁹ reviewed their medical records, and conducted the conventional clinical tests and measures appropriate to the diagnosis (such as Phalen's, Finkelstein, Tinel's, [nerve conduction studies](#) and examined an MRI of the affected extremities). Only upon evaluation of the aforementioned factors, including the reasoned exclusion of nonoccupational factors—“potential confounders” or contributing factors to the development of CTS unrelated to keyboard use—did Bleeker opine that plaintiffs' occupational use of keyboard equipment caused their development of [carpal tunnel syndrome](#). *Id.*

***38** As for defendant's contention that plaintiffs' own hand surgeons Raisis and Boulos refute Bleeker's findings, plaintiffs characterize the charge as “advancing specious and deceptive claims.” Specifically, plaintiffs note that neither surgeon offered any opinion or finding about the cause of plaintiffs' injuries. Rather, “responding to the entirely leading questions of defense counsel, Dr. Boulos prosaically and generally agree[d] that various factors, including typing activities, could ‘contribute’ to the development of [carpal tunnel syndrome](#).” In her analysis, Bleeker considered and eliminated any such “confounding factors.” Moreover, plaintiffs maintain that, as a legal matter, the existence of other such contributing agents to plaintiffs' [upper extremity injuries](#) does not negate defendant's liability for its own misconduct to the extent thus was similarly a contributing factor. D.I. 322 at 28, n. 13.

With respect to Raisis' comments that he was unaware of specific studies demonstrating the causal connection between typing and the development of CTS, plaintiffs emphasize Raisis' further remarks that it was his understanding that this connection was well accepted in “courses and personal communications with other physicians.”⁴⁰ Finally, even if defendant is accurate in his assertion that these physicians actually support IBM's contentions on the issue, the conflicting testimony in no way supports exclusion of Bleeker's testimony under a *Daubert* admissibility motion. D.I. 322 at 28–229, n. 13.

Defendant's argument that Bleeker fails to explain why plaintiffs continue to experience symptoms of CTS even after surgery is likewise unfounded, according to plaintiffs. Bleeker's deposition testimony explained that, with respect to Allen, “as the healing process goes on, ... the canal ... is not allowing her to have enough space in there,” D.I. 330,

Ex. 65 at 167, 174, and “[t]he way the transverse carpal ligament healed following surgery, that might have made ... the canal slightly smaller.” *Id.* at 317. Accordingly, Bleeker concluded that “the only reason she is continuing to suffer [carpal tunnel syndrome](#) is because of the original typing.” *Id.* at 324. The doctor further noted that Allen “returned to typing four weeks after surgery and Mrs. Bowers did not return to work until a year after surgery.” *Id.* at 190. As for Bowers' continuing symptomatology, Bleeker commented that “she did have improvement of her symptoms following surgery,” but that there was cause for concern that “she was returning to the same job with no ergonomic modifications.” *Id.* at 212–213. The doctor also stated that “one possibility which we do see is re-entrapment of scar tissue only because [Bowers] did have good relief of her symptoms when the pressure was relieved immediately following surgery” (*Id.* at 214), but following the surgery “we have a closed canal again and you are just now returning that person back to the same job which produced the condition initially, [creating] a very high chance of the individual developing the problem again.” *Id.* at 352.

*39 Plaintiffs' position is of merit. The Third Circuit has found that “most of the *Daubert* factors—testability, general acceptance, peer review, and degree of production of errors, are of only limited help in assessing whether the methodology [of a physician] is reliable (i.e., scientifically valid).” [Paoli II](#), 35 F.3d at 758. Instead, courts must consider whether:

either (1) [the doctor] engaged in very few standard diagnostic techniques by which doctors normally rule out alternative causes and the doctor offered no good explanation as to why his or her conclusion remained reliable, or (2) the defendants pointed to some likely cause of the plaintiff's illness other than the defendants' actions and [the doctor] offered no reasonable explanation as to why he or she still believes that the defendants' actions were a substantial factor in bringing about that illness.

Id. at 760.

In the case at bar, while the Court finds that although Dr. Bleeker did not eliminate every single conceivable confounding factor, her opinion was nonetheless based upon a sufficient number of diagnostic techniques to be deemed reliable. To wit, prior to rendering her opinion on each plaintiff, Dr. Bleeker: (1) conducted physical examinations of the plaintiffs; (2) recorded their medical histories and reviewed their medical records; (3) conducted the conventional clinical tests and measures appropriate to the diagnosis (such as Phalen's, Finkelstein, Tinel's, [nerve conduction studies](#) and review of [magnetic resonance imaging](#) of the affected extremities); (4) took their occupational and social histories; and (5) considered alternative causes. D.I. 363 at 11–26. Moreover, as plaintiffs correctly note, the Doctor did address the issue of why plaintiffs continue to experience CTS symptoms. Her testimony confirms that the use of the keyboard was a factor in the recurrence of the CTS symptoms.

As for defendant's alternative criticisms regarding other physicians' opinions about the causation of plaintiffs' CTS problems, specifically, the general association (or lack thereof) between CTS and keyboard use and other contributing factors, this Court finds that any such analyses go to the weight to which the testimony is entitled. Accordingly, this Court recommends defendant's motion *in limine* to exclude the specific causation testimony of Dr. Margit Bleeker be denied.

D. Dr. Robert Cunitz

Dr. Cunitz (“Cunitz”) is a human factors psychologist “specializing in the area of the safety of the interaction of people with products as they are used in the real world.” D.I. 310, Ex. A–161. In other words, he is a “warnings” expert. According to Cunitz's report on warning requirements for keyboard and computer use, specifically prepared for this litigation, “warnings of the danger of various musculo-skeletal injuries were necessary so that equipment purchasers, employers, supervisors and users could become alerted to and knowledgeable with respect to the range of known and suspected risks associated with intensive keyboard use.” D.I. 310, Ex. A–164. Furthermore, “[t]he keyboard and data entry products involved in this litigation were defective in the absence of the necessary warnings [and][t]he products involved were unreasonably dangerous because of the defects described above which could have and should have been corrected.” D.I. 310, Ex. A–164.

*40 Plaintiffs assert that Cunitz satisfies the criteria to proffer expert testimony, as demonstrated by his professional credentials, “fully informed and reliable methodology,” and past acceptance by other courts as a “warnings” expert qualified to testify on the subject. D.I. 322 at 23–24. Defendant maintains that Cunitz’s testimony should be excluded where Cunitz: (1) is not qualified to testify about the alleged causal relationship between typing on any keyboard and the development of physical injuries such as CTS; (2) fails to identify any alleged defect in the design of the keyboards used by plaintiffs; and (3) is unable to state with any specificity that a particular warning would have prevented the alleged injuries suffered by plaintiffs, instead basing his conclusions on “unsupported speculation.” D.I. 309 at 20–25.

In its determination of whether a witness may be considered as an expert, this Court must compare the “area in which the witness has superior knowledge, skill, experience, or education with the subject matter of the witness’s testimony.” *Carroll v. Otis Elevator Co.*, 896 F.2d 210, 212 (7th Cir.1990) (quoting *Gladhill v. General Motors Corp.*, 743 F.2d 1049, 1052 (4th Cir.1984)). Moreover, while an “expert may give his opinion on a particular matter within the scope of his expertise, that opinion must be based on facts.” *Randolph v. Laeisz*, 896 F.2d 964, 967–68 (5th Cir.1990).

Characterizing his “assignment” from plaintiffs as an analysis “of a general nature without emphasis on any one manufacturer or supplier or any particular claimant,” and his report as “applicable to all computer and data entry keyboard situations,” Cunitz opines that appropriate warnings would have reduced or eliminated the dangers of musculoskeletal injuries experienced by keyboard users. D.I. 310, Ex. A–163–65. The psychologist further states that responsibility for provision of such warnings lay with the manufacturers and suppliers of the computer equipment, and that keyboard and data entry products were defective and unreasonably dangerous instruments absent the cautionary notice. D.I. 310, Ex. A–164.

During his *in limine* testimony, Cunitz outlined the traditional methodology applied by human factors specialists when conducting a risk/safety analysis on a man-machine interface. According to Cunitz, the first step, a task analysis, focuses on understanding how a person interacts with a given product. Cunitz *In Limine* Hearing, D.I. 349 at 7. Specifically, a task analysis identifies the product and its essential features, as

well as the process of how the person interacts and deals with the product. Thereafter, examination of the associated safety component is conducted through such hindsight techniques as surveying the product’s prior incident, injury, accident and complaint information. D.I. 349 at 7. Additionally, foresight techniques such as failure mode, effect analyses and faulty analyses applied by systems safety professionals on the product are considered. D.I. 349 at 8.

*41 Cunitz also stated that a common concern for human factors specialists is the issue of warnings, resulting from hazard, risk and danger analyses where the hazardous (“harmful”) features of a product are identified, as well as the manner in which people may be exposed to those hazards. D.I. 349 at 8. The goal is to determine the risk and type of injury possible from a person’s foreseeable use of a particular product, and the intervention (i.e., warnings and/or instructions) required to avoid such harm. Where a human factors specialist is not an expert in all areas of harm, the appropriate expert would be consulted to assist in the aforementioned analysis. For example, if the product at issue is of a toxological nature, Cunitz would consult with a toxicologist. D.I. 349 at 8–9. With respect to the general issue of warnings and the conduct of a risk/safety analysis, there are a number of long-accepted reference articles from authoritative sources, such as the National Association of Manufacturers, the National Safety Council, the American Psychological Association and the American National Standards Institute. D.I. 349 at 10–12.

The provision of warnings serves three distinct purposes. The first purpose involves the notion of “informed consent,” that a warning allows a person to *knowingly* assume or avoid a risk. D.I. 349 at 16. The second purpose for warnings is as a safety device or behavioral guard. D.I. 349 at 16–17. Finally, warnings serve as reminders to people that they are about to encounter a dangerous situation. D.I. 349 at 17. While all warnings share a common thread, they are naturally adapted for effective communication to the population at issue, which may require consideration of cultural differences. During an assessment of whether a warning was merited in the instance of an individual’s injury from product use, i.e., as during a forensic investigation, a human factors specialist generally does not directly interview the injured party, instead usually relying on the party’s sworn deposition testimony or the like. D.I. 349 at 23. Such an approach is practiced because human factors specialists do not have substantial interview training and skills, and also because it is especially difficult to establish how a specific person who has changed as a

result of his injury might have previously acted in response to a particular situation. D.I. 349 at 12. Rather, predictions are more readily available for what groups of individuals in similar circumstances are likely to do in response to warnings. As such, Cunitz testified that a direct interview is highly unlikely to elicit any significant information not already provided through sworn deposition testimony. D.I. 349 at 24–25.

With regard to the case at bar, Cunitz conducted a general human factors task analysis to assess the need for and adequacy of warnings with respect to [musculoskeletal injuries](#) associated with the use of the computer and other data entry keyboards. To this end, he considered the nature of the equipment and the keyboard tasks involved; however, he did not examine the actual workstations. Nor did he consult with outside experts or examine the plaintiffs' respective deposition testimony. Instead, Cunitz relied on testimony from the plaintiffs' medical and ergonomic experts, although he noted that he also was provided with a substantial amount of research information in the medical and ergonomics literature. D.I. 349 at 30–34.

*42 Significantly, while generally familiar with the notion of an association between [musculoskeletal injuries](#) and keyboard use, Cunitz freely admits that his general conclusions regarding the unspecified computer keyboards, [musculoskeletal disorders](#) and the necessity of warnings⁴¹ are premised upon a series of assumptions, whose validation presumably would be provided by plaintiffs' other expert witnesses. D.I. 310, Ex. A–162. Cunitz's assumptions include, but are not limited to, that:

... the danger [of [musculoskeletal injuries](#) from keyboard use] can be reduced or eliminated if one or more of the following interventions are accomplished: (a) early identification and recognition of symptoms, (b) appropriate medical treatment, (c) changes to furniture, (d) modification of keyboard and monitor placement, (e) the use of rest breaks, exercise breaks, and other means to interrupt the continuous flow of the work, and (f) training in keyboarding techniques such as hand, wrist and arm position and maintenance of proper posture. D.I. 349 at 57.

... that the claimants involved in the litigation will have been diagnosed

as having [musculoskeletal injuries](#) associated with computer and data entry equipment.

D.I. 310, Ex. A–162–63.

Defendant's position regarding Cunitz's testimony is compelling. While Bleeker, plaintiffs' medical causation expert, may be deemed qualified to testify about the alleged *temporal* association between keyboard use and CTS, this testimony cannot bridge the quantum leap which Cunitz's assumptions mandate. Cunitz never met the plaintiffs in the case at bar, nor did he ever independently examine their workstations or keyboards at issue. D.I. 310, Ex. A–121. He further concedes that he is not addressing any alleged defect in the design of the keyboards used by plaintiffs and, significantly, agrees that he is not qualified to express any opinion with regard to the alleged causal association between typing on any keyboard and the development of CTS or any other physical injury. D.I. 310, Ex. A–12–22, 131, 141–42. Moreover, Cunitz fails to identify specific warnings which would address his concerns about the keyboards, stating in his deposition that “that's well beyond anything I would ever be asked to do.” D.I. 310, Ex. A–122. And he does not attest that any such warning would have prevented the alleged injuries suffered by plaintiffs, as evidenced by the following colloquy during his deposition:

Q: Well, are you assuming or do you know that [carpal tunnel syndrome](#) can be prevented if the user warnings that you would regard as appropriate?

A: I have assumed in my third assumption that they [sic] were things to tell people that would make a difference.

D.I. 310, Ex. A–136.

The *Schneck* court addressed a very similar proffer of testimony by a “warnings” expert, with the same dearth of supporting evidence. In *Schneck*, “warnings” expert Dr. Samuel Glucksberg (“Glucksberg”) submitted a report “in which he stated that ‘adequate and timely warnings and instructions on the safe use of keyboards to users and to supervisors would significantly reduce the risk of repetitive stress injuries in the work place.’” *Schneck* Op. at 44. In excluding Glucksberg as an expert witness, the *Schneck* court reasoned:

*43 In the present matter, Dr. Glucksberg suggests that warnings are necessary to provide product users with knowledge that would avoid or minimize the risk of injury. *See Glucksberg* Report at 4. He states that “users should be specifically warned about those [design] deficiencies and the risk that they pose for repetitive stress injuries.” *Id.* However, he provides no foundation for the premise that there are “design deficiencies” that pose a risk of injury. Instead, he simply assumes that is so. Moreover, whether users should be warned is a legal issue. Dr. Glucksberg also opines that “[a]dequate warnings [and] instructions ... can reduce the incidence of repetitive stress injuries to people at risk.” *Id.* At 5. This is a medical issue about which he is unqualified to render an opinion. Such an opinion should be given by a medical causation expert, not a psychologist. His opinion assumes there is, in fact, some evidence that has been shown to reduce this alleged risk; however, there is no evidence presented by Dr. Glucksberg to support this assumption. Dr. Glucksberg continues by stating that warnings should be given to “[s]pecify the nature and extent of the potential injuries, namely repetitive stress injuries.” *Id.* This begs the question of whether there is evidence of a danger posed by the IBM machines to require such a warning.

Dr. Glucksberg simply assumes that there is scientific evidence of a danger posed by the product giving rise to a duty to warn and that effective remedial measures exist. It is undisputed that IBM did not provide plaintiff [sic] with the kind of warnings plaintiffs claim they should have been given. This is not a case where the adequacy of a particular warning is at issue. Rather, the issue is whether the risk of harm even exists to necessitate a warning ... Thus, IBM's motion to exclude Dr. Glucksberg's testimony *in limine* is granted.

Schneck Op. at 44–45. *See also Dennis*, 927 F.Supp. at 159 (excluding Dr. Glucksberg as an expert on warnings).

Schneck thus denied the proffer of Glucksberg's expert testimony based on the same glaring deficiencies in supporting evidence that this Court now faces with regard to Cunitz. In light of these circumstances, and where it is well recognized that an expert opinion must be based on facts, rather than premised on unsupported assumptions and speculation, the Court recommends that Cunitz's testimony be excluded in its entirety.⁴²

E. Extraneous Arguments Regarding the Admissibility of Plaintiffs' Expert Testimony

Plaintiffs submit two further arguments beyond the *Daubert* analysis regarding the admissibility of their experts' testimony. Specifically, they contend that: (1) where a Minnesota state court reviewing a similar RSI action allowed plaintiffs' experts to testify upon analysis under the more rigorous *Frye* standard, the testimony should necessarily be admitted in the case at bar; and (2) plaintiffs' expert testimony is subject to judicial notice by the Court.⁴³ D.I. 322 at 36–41. Defendant refutes these contentions, citing the *Schneck* opinion, which squarely rejected the plaintiff's same evidentiary arguments. D.I. 334.

*44 With regard to the plaintiffs' success under the *Frye* standard applied by the aforementioned Minnesota state court in *Urbanski v. IBM*, this Court concurs with *Schneck* that:

[w]hile the *Urbanski* court found that the proffered testimony “may meet [*Frye's*] requirements of reliability and trustworthiness,” *Urbanski* slip op. at 9 (citations omitted), such findings are by no means persuasive as to whether the experts in this case pass muster under *Daubert/Paoli II*. Plaintiffs' suggestion that this Court is somehow bound by the Minnesota state court decision in *Urbanski* is wholly without merit.

Schneck Op. at 47–48.

As for plaintiffs' alternative argument that the expert testimony is subject to judicial notice, the Court finds this novel argument unsupported by case law and therefore rejects same. As the *Schneck* court so aptly stated:

plaintiffs argue that “[t]he scientific techniques, implied in this case, epidemiology, differential medical diagnosis, and product design evaluations, are based on ‘well established propositions,’ and ‘are subject to judicial notice.’” Plaintiffs have not, and indeed can not (sic), come forward with any authority to support this novel argument. In fact, in each case cited by plaintiffs, the proffered evidence was subjected to some type of judicial scrutiny and was not received into evidence without the requirements of formal proof. Plaintiffs' unsubstantiated argument, therefore, fails to defeat IBM's motion for summary judgment.

Schneck Op. at 50 (citations omitted).

III. Do IBM's Keyboards Suffer from Defective Design?

Plaintiffs argue that the evidence clearly demonstrates the minimal requisite of the existence of some defect in defendant's product taken as a whole, regardless of whether their proposed liability experts are allowed to testify. According to Bowers and Allen, with respect to a question of design defect, a plaintiff need not even identify with specificity any particular feature or component of the product that is defective. D.I. 322 at 33. See generally *Towe v. Justis Brothers, Inc.*, 290 A.2d 657, 658 (Del.Super.1972); *Voss v. Black & Decker Inc.*, 59 N.Y.2d 102 (1983).

Defendant counters that the record provides no support for plaintiffs' allegations of a defective keyboard design by IBM, and that plaintiffs' reliance on *Towe* for the proposition that they need only establish a defect in the product "taken as a whole" is misplaced. Specifically, *Towe* merely states that on a motion to dismiss, as opposed to summary judgment as the case at bar, a plaintiff must only show some evidence of a defect, a minimum proffer plaintiffs have failed to satisfy.⁴⁴ D.I. 334 at 16, n. 29.

The Court agrees with defendant. It is well recognized that in a negligence case under Delaware law, a plaintiff must establish a duty, breach of that duty, proximate cause and damages. See *Hubscher v. Pantzer Management Co.*, C.A. No. 93–244–SLR, slip op. at 4 (D.Del. Aug. 25, 1995); *Croom v. Pressley*, C.A. No. 93C–01–026, slip op. at 4 (Del.Super. Jul. 29, 1994). These elements must be established by a plaintiff in both "defective design" and "duty to warn" claims in a product liability action. *Macey v. AAA–1 Pool Builders & Serv. Co.*, C.A. No. 88C–JN–10 (Del.Super. Apr. 30, 1993). Proof that a product is defective necessitates more than merely showing that the product brought about an injury.

*45 While the potential presence of a defect in IBM keyboards is a matter of first impression in this Court, the New Jersey court in *Schneck*, and more recently in *Reiff v. Convergent Technologies*, C.A. No. 95–3575(JEI) (D.N.J. February 28, 1997), considered whether the plaintiffs had met their burden of establishing a design defect in computer keyboards. *Schneck* Op. at 3; *Reiff*, Op. at 9–14. Significantly, the respective New Jersey and Delaware laws applicable to product design defects are remarkably similar. To wit, under New Jersey law, in order for a plaintiff to establish a design defect, he must prove that the product was not "reasonably fit, suitable or safe for its intended purpose because it ... was designed in a defective manner." *Schneck* at 3. A "risk-utility analysis" must be applied, with the

result that a manufacturer is held liable only "if the danger posed by the product outweighs the benefits of the way the product was designed and marketed." *Schneck* at 4. In other words, to establish a product defect under New Jersey law, proof of either a design defect, a manufacturing defect or an inadequate warning defect, which renders the product unfit, unsuitable or unsafe for its intended or prescribed purpose must be established. *Reiff*, at 9. Similarly, in Delaware, a product is defective in design where it is not reasonably fit for its intended purpose and where the design has created a risk of harm which is so probable that an ordinary prudent person, acting as the product's manufacturer, would pursue a different available design to substantially lessen the probability of harm. *Dillon v. General Motors Corp.*, 315 A.2d 732, 736 (Del.Super.1974), *aff'd*, 367 A.2d 1020 (Del.Super.1976); *Nacci v. Volkswagen of Am. Inc.*, 325 A.2d 617, 620 (Del.Super.1974).

The *Schneck* court found that plaintiffs had not "stated how ... the IBM machines are defective."⁴⁵ Particular emphasis was placed on Kroemer's failure to identify a defect present in the keyboards used by plaintiffs:

While Dr. Kroemer discusses design defects in "conventional keyboards," his testimony fails to include any reference to or discussion of specific design defects in the IBM machines. Rather, Dr. Kroemer discusses the three general "defects" of "the conventional keyboard." According to Dr. Kroemer, the defects of the conventional keyboard are: too many keys; unergonomic arrangement of keys; and insufficient space to rest wrists. *Id.* However, all three alleged defects are sufficiently generic that Dr. Kroemer apparently feels he can testify about them without having ever examined the IBM machines used by Mrs. Schneck, inspected the workstation at which she used the IBM machines, or observed her keying techniques. *Schneck* at 11.

Similarly, the court in *Reiff* determined no bridge was provided by plaintiff's expert, Dr. Hedges, between noncompliance with industry or design specifications and liability under New Jersey product liability law stating that "[p]roducts that fail to meet these [ANSI] or other such standards may well be defective in the engineering sense, but are not necessarily defective in the products liability sense." *Reiff* at 11.

*46 Plaintiffs in the case *sub judice* likewise fail to identify any defect in the design of IBM keyboards, either

generally or with particular regard to the actual keyboards used by Allen and Bowers. Assuming, *arguendo*, that *all* of plaintiffs' proffered liability experts were deemed satisfactory under *Daubert/Paoli II* to offer testimony, there is still no evidence that specifically identifies and addresses any alleged keyboard defects demonstrating that the keyboards in question were not fit for their intended purposes. Nor does the record suggest that the IBM products at issue failed to comport with the standards of a reasonably prudent manufacturer.⁴⁶ Significantly, the aforementioned experts, in particular Kroemer and Cunitz, did not even examine plaintiffs' keyboards, workstations, types of tasks performed or typing techniques. Although Kroemer's report of August 1995 (D.I.352, Ex. 78) was admitted during the *in limine* hearing, it provides very limited information regarding QWERTY or conventional keyboard design. Upon review, the report addresses in general five "groups of concerns" regarding keyboard designs, which in essence fall within the broad categories addressed in *Schneck*.⁴⁷ Further, as noted by Kroemer during his *in limine* hearing in this case:

Keyboard use is, of course, a rather complex issue. One would have to probably observe persons operating keyboards.

That would require a—an observation of a person or persons performing *one or several jobs*.


D.I. 359 at 161 (emphasis added).

Moreover, to evaluate the keyboard in question, measurements should be taken, in addition to a comparison with other similar keyboards. D.I. 359 at 164–165, 167–171. These measurements are necessary to compare the distance between key centers with standards, to know the space displacement characteristics of the keys, to determine the tilt or angle involved, to ascertain that the majority of the keys are at elbow height of the operator for comfort of use and if the potential operators are unknown, to determine adjustment angles as compared with various elbow heights. D.I. 359 at 168–170.

Keyboard use, one of the five factors employed by Kroemer in his evaluation, requires the evaluator to not only visually observe the operator, but also to take certain measurements over a period of time, which include the extent and intensity involved in performing a particular task, the relationship and availability of rest breaks in completing the work, the number of strokes performed, and the actual activation of keys being

applied by the operator in comparison to design values. D.I. 359 at 171. As a result, Kroemer's analysis of the presence of design defects and the relationship to the development of repetitive stress injuries in general require both observation of the operation and measurements of the keyboards in question, neither of which occurred in this case. D.I. 359, 158–159.

In addition, it is abundantly clear that keyboard use by the operator, including posture, positioning of the upper limbs and fingers, and *stroke* pressure applied play a significant role in the development of repetitive stress complaints and injuries, which are not related to the function or design of the keyboard. D.I. 310, Ex. 21 at 116; D.I. 363 at 19–20, 52, 91–92, 94, 125–27.

*47 While plaintiffs submit patent applications of alternative design keyboards to apparently suggest that there are more ergonomically appropriate alternatives in existence, plaintiffs' experts do not attest to the virtues of such designs. Further, there is no suggestion therein that the available alternatives would have prevented the injuries allegedly suffered by plaintiffs. D.I. 325, Ex. 32, 33, 34, 35. Indeed, plaintiffs' causality expert, Bleeker, admitted that "alternative" design keyboards were new, and that consequently there are no studies which reflect whether these designs would prevent or lessen incidents of CTS. D.I. 310, Ex. A–90 at 330–32.⁴⁸ Thus, the record simply does not support plaintiffs' claim of the existence of a defect in IBM's keyboards which allegedly caused the incurred CTS injuries, and that the risk of harm was so probable that a manufacturer should pursue an alternative, available design which would substantially lessen the probability of that harm.  *Nacci*, 325 A.2d at 620.⁴⁹

IV. Did Defendant Have, and Breach, a Legal Duty to Warn? Plaintiffs purport that defendant knew or should have known about all potential dangers of its keyboards to users and foreseeable misusers—as evidenced by IBM internal documents suggesting company recognition of the allegedly hazardous relationship between continuous, repetitive keyboard use and CTS, and had a legal duty to warn which steps must be taken to avoid *possible* harm.⁵⁰ See, e.g., *Graham v. Pittsburgh Corning Corp.*, 593 A.2d 567, 569 (Del.Super.1990). Where defendant failed to provide the appropriate warning, the company is liable for the injuries incurred by the plaintiffs. D.I. 322 at 33.


Defendant counters that it had no duty to warn because there is nothing inherently dangerous about its keyboards, and a manufacturer's legal duty to warn purchasers about a particular product arises only if there is an inherent danger in the product. *Betts v. Robertshaw Controls Co.*, C.A. No. 89C-08-028, slip op. at 5 (Del.Super. Dec. 28, 1992). Courts overwhelmingly have held that keyboard manufacturers have no duty to warn, particularly where a plaintiff's use of a keyboard in a repetitive and rapid manner—thus potentially resulting in symptoms associated with [carpal tunnel syndrome](#)—is characteristic not of the keyboard, but of that plaintiff's work habits. *See, e.g., Finley v. NCR Corp.*, Civ.No. 9205242, slip op. at 11-14 (D.N.J. Jan. 23, 1996); *Doll v. Digital Equipment Corp.*, C.A. No. 93-CV-0359E(M), slip op. at 7-9 (W.D.N.Y. Mar. 1, 1996); *Reiff* at 14-17. Moreover, in order for a failure to warn claim to succeed, a plaintiff must also offer sufficient evidence indicating that the lack of an adequate warning was a proximate cause of the claimed injuries. *Id.* Where in this instance plaintiffs have failed to prove such proximate cause, relying on their warnings expert's "vague allegations that repetitive use of the product, or the positioning of the product being used, is the cause of their injuries," plaintiffs' failure to warn claim must be dismissed. D.I. 309 at 30-34.

*48 Defendant's argument is persuasive. Delaware law pertaining to the duty of a manufacturer to warn purchasers of inherent dangers in its products follows the [Restatement \(Second\) of Torts § 388 \(1965\)](#), which provides that a manufacturer's warning to a third person is required when it:

(a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Betts, slip op. at 4 (quoting [Restatement \(Second\) of Torts § 388 \(1965\)](#)).

Delaware courts interpreting this provision have held that "the standard for determining the duty of a manufacturer to warn is that which a reasonable (or reasonably prudent) person engaged in that activity would have done, taking into consideration the pertinent circumstances at that time."⁵¹ *Graham v. Pittsburgh Corning Corp.*, 593 A.2d 567, 571 (Del.Super.1990). Delaware courts have further held that a manufacturer is not required to warn a consumer about potential harm which is open and obvious to the user of the product. *Farm Family Mut. Ins. Co. v. Perdue, Inc.*, No. 416, 1990, 1992 Del. LEXIS 27 at *5 (Del.Supr. Jan. 2, 1992) ("Under Delaware law, the duty to warn extends only to those who can reasonably be assumed to be ignorant of the danger.").

Moreover, "there is no duty to warn about the physical manipulation inherent in the use of certain objects which can in some persons and under some circumstances cause CTS." *Finley*, Civ. No. 92-5242, slip op. at 12 (citing *Creamer v. IBM Corp.*, No. 89-1026, slip op. at 6-7 (3rd Cir. May 18, 1989)); *see also Reiff* at 14-15; *Schneck* at 58; *Doll*, C.A. No. 93-CV-0359E(M), slip op. at 8; *Hopkins v. NCR Corp.*, 1994 WL 757510 at *9 (M.D.La.1994), *aff'd*, 53 F.3d 1281 (5th Cir.1995). Therefore, the threshold issue for consideration in such a case is "whether plaintiffs have proffered sufficient evidence to establish that the alleged danger is not simply the repetitive motion required to use defendant's products. If plaintiffs cannot make such a showing, then their failure to warn claim must be dismissed as a matter of law because defendants would have no duty to warn against any such danger." *Schneck* at 58. *See also*  *Griesenbeck v. American Tobacco Co.*, 897 F.Supp. 815, 820 n. 3 (D.N.J.1995) ("[W]ithout a duty to warn, there cannot be any failure to warn.").

Thus, in *Hopkins*, the court dismissed the plaintiff's claim that the operation of a proof encoder⁵² caused her to develop CTS, opining that there was no particular characteristic of the machine which directed the manner by which the plaintiff used the machine. 1994 WL 757510 at *9. Consequently, the defendant machine manufacturer could not be held liable for a failure to warn, as "the mere fact that plaintiff in this manner had to perform rapid, repetitive manual tasks in order to operate the proof encoder, standing alone, can not (sic) give rise to a duty to warn that such activities could cause CTS." *Id.* Applying the analysis performed by the *Creamer* court, which dealt with the issue of CTS allegedly resulting from the use of a grocery checkout scanner, the *Hopkins* court recognized

that repetitive motion “may indeed be the cause-in-fact of plaintiff’s CTS,” but significantly refused to determine it to be “the proximate cause of plaintiff’s CTS,” articulating that:

*49 Such a holding [that there was proximate cause] would necessitate a warning on any object that involves extended manual manipulation inherent in the ordinary use of the object. For example, sport equipment, computers, video games, remote controls, calculators, musical instruments, appliances, garden tools, writing utensils, kitchen utensils, workman’s tools, and indeed, *Creamer’s* exemplar milk cow, would all be deemed “unreasonably dangerous” products.

Id. See also *Creamer*, No. 89–1026, slip op. at 6–7.

In fact, other courts addressing this issue have followed the aforementioned rationale, holding that there is no duty to warn the users of equipment where the alleged injury results simply from overuse of the product. To wit, the *Doll* court found no duty to warn about the alleged dangers associated with the use of the defendant’s keyboard. C.A. No. 93–CV–0359E(M), slip op. at 8–9. According to the *Doll* court,

The fact the plaintiff may have used the defendant’s keyboard in a rapid and repetitive fashion is a characteristic not of the keyboard but of the plaintiff’s work habits and, possibly, the requirements placed upon her by her employer. The defendant is not an insurer for such activity, or responsible for such. *Hopkins*, *supra*, at 19. Were it so, every carpenter would have a claim arising from every hammered thumb, golfers would spend more time in litigation than on the links and pianists would strive to get to court rather than to Carnegie Hall.

Id. at 7. See also *Finley*, Civ. No. 92–5242, slip op. at 11 (“To declare that keyboards are not reasonably safe seems inappropriate in a society in which toys sold for the amusement of children are potentially more dangerous.”).

This rationale was recently affirmed in *Reiff* wherein the district court noted “products whose use require physical activity often entail a risk that such use will cause harm,” that

harm is from the manner of use, rather than from the product itself. In explaining the concept of use versus the product itself by the analogy to a snow shovel, Judge Irenas commented “[F]or the same reasons, the law does not and ought not require that computer keyboards contain warnings relating to a keyboard’s use in a particular way, by a particular person with particular physical characteristics and work habits.”

In the case at bar, plaintiffs offer no evidence to suggest that defendant bore a duty to warn about the dangers associated with its keyboard use under Delaware law, and then breached such duty. Plaintiffs merely set forth vague allegations that the repetitive use or their manner of use of the IBM keyboard, or the positioning of the keyboard while being used, resulted in injury. Indeed, when queried about what was injurious about the keyboards at issue, plaintiffs’ warning expert, Dr. Robert Cunitz, responded that a number of factors totally unrelated to the keyboards themselves contributed to plaintiffs’ medical problems:

*50 Q: You’re talking about a combination of the chair in which the user sits, the table or surface in (sic) which the equipment is placed, the location or angle of some of the equipment, the location of the screen, all those factors?

A: Right.

Q: Any other?

A: There are other factors that I—that I know we left out, which is lighting.

D.I. 310, Ex. A–120–21.

Cunitz also testified:

A: ... it’s one thing to design a keyboard that by itself feels comfortable and easy to use. I think your clients [IBM] have probably done about as good a job doing that, at least in my professional experience, as a layperson, that they seem to do very well at that. So it’s comfortable. At least so it seems.

D.I. 310, Ex. A–120.⁵³

Interestingly, neither Cunitz nor plaintiffs' other liability experts examined or tested the IBM keyboards at issue to determine any possible defects. They also made no effort to quantify the number of keystrokes per period of time used which allegedly resulted in plaintiffs' injuries, or to observe plaintiffs' working at the IBM keyboards to support their conclusions about the ergonomics of plaintiffs' workstations or plaintiffs' posture, while typing. Given this unexplained circumstance, and in light of the aforementioned testimony by warnings expert Cunitz, who admittedly only *assumes* that a warning would have prevented the injuries,⁵⁴ the Court must conclude that plaintiffs' injuries resulted from the repetitive motion involved with typing on the IBM keyboards. As such, where this scenario is essentially no different than those presented in *Schneck*, *Finley*, *Creamer*, *Reiff*, *Doll*, and *Hopkins*, the Court is compelled to find similarly, that: (1) defendant's keyboards are not inherently dangerous instrumentalities, where the only "danger" associated with the keyboard use is the continuous repetitive motion and (2) that defendant consequently is under no duty to warn about the keyboard use, where Delaware law imposes no "warning" obligation regarding "the physical manipulation inherent in the use of certain objects which can in some persons and under some circumstances cause CTS." *Also see* *Schneck* Op. at 63–64 (citing *Creamer*, slip. op. at 6–7).

As a final comment, it again should be noted that under Delaware law, a defendant is not required to warn a consumer about potential harm which is open and obvious to the product's user. *Farm Family Mut. Ins.*, 1992 Del.LEXIS 27 at *5. The *Finley* court addressed this issue with regard to keyboard use and injury thusly: "... warning persons from using keyboards beyond a tolerable level of pain seems beside the point. Like most things that produce pain, it should be self-evident that a pain-producing activity is a threat to health." *Finley*, slip op. at 11. *See also* *Doll*, slip op. at 8 ("the defendant was not required to warn against the open or the obvious").

V. Did the Use of Defendant's Keyboards Proximately Cause Plaintiffs' Injuries?

*51 As previously discussed, in a negligence action or products liability claim, the plaintiff must prove all elements of the claim, including that of proximate causation. The establishment of proximate cause "requires that the plaintiff prove that but for the *tortious* conduct of the defendant, the injury which was suffered would not have occurred." *Hubscher*, slip op. at 4 (emphasis added). Plaintiffs maintain

that the CTS symptoms incurred resulted from the use of defendant's allegedly *defectively designed* keyboard, as evidenced by their causation expert, Bleeker, who concluded causation from the strong temporal association between the plaintiffs' use of the keyboards in question and the onset of symptoms. However, as discussed in the preceding sections, before addressing causation, there must be a finding of a duty owed and a breach of that duty—in other words, there must be evidence of defective design and a duty to warn. In light of this Court's previous findings of an absence of either defective design or duty to warn, the issue of proximate cause need not be addressed.⁵⁵

VI. Related Issues

As highlighted previously herein, plaintiffs heavily emphasize defendant's knowledge of the alleged hazards of keyboard use, acquired from internal and external studies and internal worker's compensation claims for RSI injuries. D.I. 322 at 6–12. IBM does not disclaim its longstanding cognizance that repetitive use of keyboards may result in upper extremity fatigue and injury.⁵⁶ Indeed, the company actively sought such inquiry. Nor does IBM challenge plaintiffs' assertion that other keyboard manufacturers have provided instructions and warnings regarding keyboard use. D.I. 334 at 3–6. Rather, IBM claims that the documents cited by plaintiff are not dispositive evidence of design defects in the IBM keyboards at issue and a duty to warn on the part of IBM. D.I. 334 at 4.

These documents cited and relied upon by plaintiffs will be discussed seriatim.

Exhibit 5.

This exhibit (D.I.323) appears to be an article related to the safety reports of visual display terminals (VDTs) addressing a number of possible health concerns, including radiation exposure, vision, cumulative trauma, skin disorders, and other matters. Specifically, at pages 12 and 13, in a question and answer format, it discusses CTD, RSI and CTS.⁵⁷ Although this brief Q & A addresses keyboard use, it emphasizes positioning, posture, workplace design and proper set up. The article specifically states that "VDT keyboards, per se, do not cause work disorders [CTS]," but relates the development of such condition to any prolonged repetitive motion, noting that prevention may be accomplished through appropriate workstation design and body positioning. As evident from this article, there are numerous issues regarding CTDs and

keyboard use. In fact, they are infinite as evidenced from the materials submitted in this matter, in particular the various abstracts by Cunitz. Nothing in the exhibit identifies scientific evidence supporting a causal connection between the keyboard and carpal tunnel syndrome. At the most, the exhibit represents an effort to provide guidance on what a VDT user could do to be comfortable in the workplace. Therefore, the articles does not exhibit a causal relationship between keyboard use and *carpal tunnel syndrome*, and is irrelevant to the issues under consideration.

Exhibits 6 and 7.

*52 These two exhibits (D.I.323) are essentially the same and are 1984 summaries discussing the Australian experience. They fail to establish a causal relationship between keyboard use and CTS. Further, the language cited by plaintiffs' counsel is followed by such qualifying comments:

The occurrence of the disease [tenosynovitis] is not universal, and individual susceptibility may depend on many general health and environmental factors.

D.I. 323, Ex. 6; Ex. 7 at 8 (emphasis added).

Further, these same exhibits were submitted in the *Schneck* case with that court noting that “the perception that workers were suffering injury due to keyboard operation ultimately proved to be false in Australia,” relying upon an extensive study in the September 7, 1987 issue of *The Medical Journal of Australia*. *Schneck* at 56–57. Therefore, not only do these exhibits reference a multifacet condition arising as a result of a number of factors, the findings were subsequently determined to be inaccurate. Unidentified are any design defects or proof that keyboards are likely to be dangerous for the use for which they are supplied.

Exhibit 9.

This exhibit (D.I.323) contains two internal memoranda regarding the issue of RSI in Japan. They discuss the Japanese Ministry's guidelines regarding VDT operation, IBM's response to those suggestions, and translation concerns. The isolated and incomplete quote lifted by plaintiffs from the memos does not constitute an admission that IBM Japan deliberately suppressed safety guidelines. The memoranda

only concern VDT operations in Japan and the guidelines identified therein only address VDT use in general. No relationship is established between keyboard use and injury. Again, for the reasons discussed in Exhibits 6 and 7, this exhibit does not establish a design defect or a duty to warn, nor an admission of either.

Exhibit 8.

Within this exhibit (D.I.323) is a lengthy discussion of the legal avenues available to a plaintiff under Australian law, but fails to even speculate as to the cause or causes of RSI. Nor does it articulate any legal obligation to warn IBM employees or others about VDT use under Australian law or any other country's law, including the states within the United States.

Exhibit 10.

Exhibit 10 (D.I.323) involves a letter and series of memoranda related thereto in which an IBM employee attempted to obtain a grant from IBM to Ohio State University to determine the genesis of CTD and provide “technical parameters for change in workstation design, tools, methods and processes to combat CTD.” The focus of the related memoranda and exhibits are on RSI type conditions occurring in supermarket employees using optical scanners. Plaintiffs' limited quote from this exhibit is taken completely out of context and provides no proof or admission of a design defect or duty to warn.

Exhibit 11.

The majority of this exhibit (D.I.323) relates to the development of RSI in supermarket employees using optical scanners. Plaintiffs' minimal quote is again taken out of context and is clearly irrelevant to the issues herein. For the reasons expressed in relation to Exhibit 10, this does not show either defective design or an obligation to warn.

Exhibit 12.

*53 These documents discuss IBM's funding of an ergonomics research program in the grocery industry. Contrary to plaintiffs' representations, rather than the quoted language being IBM's concern of “hiding behind,” its lawyers regarding *RSI occurrence with grocery check-out employees*, this statement made by a third party was simply designed to induce IBM to contribute to the Food Marketing Institute's research efforts. Again, this exhibit is also irrelevant.

Exhibits 13 and 14.

These two exhibits (D.I.323) are related, at least from the plaintiffs' perspective, and include testimony at state hearings in 1983 on health and safety questions of VDTs (Ex. 13) and the deposition testimony of Dr. Hirsch (Ex. 14), during which he was cross-examined about this testimony. Neither of these documents establish a design defect nor a duty to warn. Apparently, they are cited by plaintiffs, as the previous exhibits are, in support of the proposition, of the safety concerns regarding VDTs and IBM's awareness of the RSI issue and alternative keyboards. First of all, exhibit 13 addressed not only musculoskeletal stress, but also the concerns related to potential radiation exposure and vision, as well as the studies related thereto. The comments made therein show that a number of factors contribute to workplace comfort or discomfort, unrelated to the work tool itself, and are not inconsistent with the previously examined testimony of plaintiffs' experts. At most, this testimony attempts to "set out the complex issue of what had commonly become known as 'repetitive stress injury' (RSI) or 'cumulative trauma disorders' (CTDs)." *Schneck* at 52–53. It reflects that for this complex issue, there is no single solution, but rather a host of considerations, most of which are directed to modifications of the working environment. Exhibit 13 does not constitute as an admission that VDTs, including the keyboard, were dangerous.

Exhibit 14 is used by plaintiffs to support their argument that Dr. Hirsch, an employee of IBM in its Human Factors Engineering Department, was aware that the alternative split keyboard design alleviated injuries. No where in the deposition, in particular at the cite referenced by plaintiffs, does Dr. Hirsch admit that he knew that the alternative split keyboard design reduced or eliminated injuries. Further, plaintiffs' own expert, Dr. Bleeker, in addition to enumerating a plethora of elements producing RSI, testified that there is no scientifically recognized study confirming that such a design will alleviate or reduce RSI. Moreover, exhibit 14 was not authored by Hirsch. D.I. 323, Ex. 14 at 63. And, although Dr. Hirsch stated the unrefuted and admitted awareness by IBM of some relationship between RSI and keyboard use, he also maintained that the relationship between hand and arm pain and keyboard design was poorly understood. D.I. 323, Ex. 14 at 169–70. In fact, his personal understanding of that relationship was "[t]here may be no—or minimal—connection between the reported ailments [RSI] and keyboard engineering." *Id.*

Exhibit 15.

*54 This exhibit (D.I.324) contains the provisional statements of the WHO (World Health Organization) on occupational health hazards in the use of visual display units (VDUs) resulting from a conference held in Geneva, Switzerland, December 2–6, 1995, during which the following working agenda was considered and adopted: (1) the definition and classification of VDUs, (2) user characteristics, (3) review of *alleged* problems and biological explanation of health related disorders, (4) measurements of potential hazards, (5) prevention and control strategies, and (6) conclusions and recommendations. The health concerns addressed included adverse pregnancy outcomes, eyes and vision, [musculoskeletal disorders](#) and skin disorders. The first quote upon which plaintiffs rely was lifted from the WHO's press release, and is directed generally to *potential* health concerns, and not just RSI or [carpal tunnel syndrome](#). Further, the press release language recognizes a *public* awareness of possible health issues regarding VDU use. It is not limited to keyboards. Further, the provisional statement heading "[musculoskeletal disorders](#)" from where plaintiffs' limited quote is taken provides:

The working group recognizes that musculoskeletal discomfort is commonplace in VDU work. Injury from repeated stress to the musculoskeletal system is plausible. Such effects have been observed in other jobs. Further research on the potential for injury is warranted. However, the group emphasizes that these conclusions should not be interpreted to mean that musculoskeletal discomfort inevitably leads to injury or is necessarily a sign of injury. It is the view of the working group that musculoskeletal problems in VDU work are largely preventable and that appropriate control measures should be introduced. These include the application of ergonomic principles to the design of the workplace equipment, environment and work organization. Occupational health services play a key role in the

early recognition and prevention of musculoskeletal problems in VDU work.

Not only is the quote upon which plaintiffs rely taken out-of-context, but plaintiffs' emphasis is misplaced. When reviewed in its entirety, the reference to [musculoskeletal disorders](#) is not limited to the upper limbs, nor directed to a particular condition. No linkage is established between VDU design, in particular keyboard design, and the development of [musculoskeletal injury](#), specifically CTS. In fact, the summary comments only that stress to the musculoskeletal system "is plausible," further research "is warranted" and that the conclusions therein "should not be interpreted to mean that musculoskeletal discomfort inevitably leads to injury or is necessarily a sign of injury." Rather than this exhibit proving that use of a VDU or keyboard is a substantial factor in causing [carpal tunnel syndrome](#), it indicates the opposite and recognizes the numerous other contributing factors to the development of musculoskeletal *discomfort*. It does not determine that injury necessarily results from VDU use. There is no suggestion of a causal relationship between keyboard use and injury, of any design defect, or a dangerous condition inherent in VDUs.

Exhibit 16.

*55 Identified by plaintiffs as the Pincas report (D.I.324), this exhibit is a pre-publication draft of Processor Pincas, analyzing the possible legal exposure that could exist to manufacturers of VDTs. It expresses a number of potential harms consistent with computer use, most of which are not the injuries involved in this matter. No attempt is made by Professor Pincas to include the scientific basis for the alleged associated injuries. Nor is it shown that she is qualified to opine on alleged design defects. The article also discusses a variety of possible legal theories, including strict liability, which is not applicable in this case. Her analysis only addresses whether, based on her review of case law, liability under some legal theory may arise. Although she may find liability based upon unsubstantiated assumptions, her conclusion is not relevant to the issues addressed herein.

Exhibit 17–20.

These exhibits (D.I.324), along with exhibits 59–63 (D.I.326), relate to other manufacturers's warnings and will be addressed later herein. Exhibit 17, as with the other documents attributed to IBM, does not amount to an

admission of a causal relationship between keyboard use and injury, as so aptly argued by plaintiffs. Further, as discussed previously, none of plaintiffs' experts, in particular Cunitz, ever addressed the type of warning required nor identified, beyond some vague danger surrounding the activity of typing or keying what about these activities is dangerous. Certainly, IBM by exhibit 17 has not admitted to any danger in such activities. Rather, the exhibit provides suggestions for comfort in using a computer terminal—all of which are common sense suggestions.

Exhibits 21 and 22.

The article contained therein (D.I.326, Ex. 21) is a state-of-the-art review by Stephen Zoloth, Ph.D., an individual who, although used to support Punnett's analysis, has not been identified as an expert in this matter, in particular, state-of-the-art. The report is undated and an opinion by a third-party, not an admission by IBM. Further, noted within this document, Zoloth comments from a public health, non-legal view

It is an axiom of Public Health that, long before a causal link can be conclusively demonstrated between a potential risk factor and disease, it is prudent practice to intervene to reduce or eliminate exposure.

D.I. 324, Ex. 21 at 6.

The affidavit of Dr. Pascarelli (D.I.324, Ex. 22), which plaintiffs submit as evidence that the design flaws contributing to carpal tunnel syndrome as sustained by plaintiffs are common to all QWERTY keyboards, such as the IBM keyboards, is an attempt to introduce expert testimony from a witness who was never previously identified in this litigation to testify on this issue. He has not been subject to deposition and he was not presented for examination by plaintiffs during the *in limine* hearings—the hearings which plaintiffs demanded to enable them to qualify their propounded experts under *Daubert/Paoli II*, after their answering brief was filed. Pursuant to the various scheduling orders, [Fed.R.Civ.P. 56](#) and [Fed.R.Evid. 702](#), his affidavit is not admissible, and will not be considered by this Court.

Exhibit 23.

*56 This exhibit contains part of an article in the publication, *Practical Ergonomics*, alleged to be authored by D.O.B. Dickerson, IBM's former Director of Corporate Health. The copy provided of this document is not only incomplete, the identity of the author and the date of publication is unknown. Plaintiffs' quotes from this article regarding *tenosynovitis* follow an incomplete sentence regarding "workplace layout," with no apparent reference to keyboard defects. And, no where does the article suggest that the unknown author opined that Kroemer's studies were reliable. Further, the other quotes attributed by plaintiffs to be the opinion of the author are not. Rather, they are merely statements of findings made by others. Therefore, even if this exhibit was authored by Dr. Dickerson, it does not reveal his opinion on design defects, nor a causal connection between keyboard use and RSI. This unauthenticated document is not admissible and shall not be considered by this Court.

Exhibits 24 and 25.

Exhibits 24 and 25 have been addressed in the discussion concerning exhibit 7. In fact, Exhibit 25 is essentially the same as exhibit 7.

Exhibits 26–31.

Plaintiffs' reliance upon these exhibits as evidence of defective keyboard design is misplaced. Some of these materials include comments and suggestions by third parties. Devoid from these exhibits are any statements by IBM regarding a causal connection between the use of its keyboards and *carpal tunnel syndrome*. These documents discuss matters such as posture, positioning, standing, sitting, overall comfort, workplace set up, footrests and chairs. Even the quotes upon which plaintiffs rely, which the Court must assume were the best plaintiffs could gleam from this massive quantity of paper do not support that the specific IBM keyboards involved in this matter caused *carpal tunnel syndrome*, that any of its keyboards caused *carpal tunnel syndrome*, that RSI or *carpal tunnel syndrome* resulted from defectively designed IBM keyboards or that there were common design defects in all standard keyboards.

Similarly, Exhibit 29, a proposal submitted by a third-party and not authored or attributable to IBM, contains a list of various occupational and non-occupational activities and factors which contribute to the development of RSI, such as, "age, gender, vitamin deficiency, size, posture, ergonomics and physical condition ."

Like a significant number of exhibits previously addressed, these documents merely comment upon keyboards and some alleged assumption between keyboard use and RSI.



Exhibit 28 contains IBM workers' compensation records submitted in support of causation. A review shows "nothing more than that claims were being made that musculoskeletal complaints were related to keyboard use." *Schneck* at 53. No keyboard defects are indicated. Plaintiffs reference that these records definitively show that the cause of injury was a "keyboard," thereby proving design defects common to all keyboards is totally without merit. These forms are routinely completed by some unidentified IBM personnel and are usually required by state law. A review of the entire document shows that they are recordings of hearsay statements by a complainant, which became part of an employee's worker's compensation file. There is nothing to support that those forms were reviewed or executed or admitted as accurate by a corporate officer from IBM. No where on these forms is there any representation identifying any defect in the keyboard. Nor is there any reference to the keyboards involved in those claims and whether those keyboards were similar to or the same equipment used by plaintiffs. They neither support a finding of causation nor an admission on the part of IBM. *Schneck* at 54, citing *Karolisyn–Morris v. IBM*, Index. No. 14003/92, mem. op. at 7 (N.Y.Supr. January 31, 1994).

*57 The *Schneck* court addressed substantially similar (and in some instances, identical) evidence submitted by the plaintiffs in support of their product liability claim. With regard to defendant's internal memoranda proffered to demonstrate the recognition and intentional disregard of the relationship between RSI and IBM keyboard use, the court held "[t]he documents plaintiffs' counsel proffers do not amount to an admission of a causal relationship between keyboard use and injury. If anything, they demonstrate IBM was attempting to sort out the complex issue of what had commonly become known as ... RSI ..." See *Schneck* at 51–57. As for Bowers and Allen's assertion that other manufacturers' enclosed warnings about proper keyboard use and risk of injury, when faced with similar materials, *Schneck* found that "the documents regarding instructions, warnings, and alternative keyboard products of other manufacturers are irrelevant to [plaintiffs'] action against IBM and, hence, are irrelevant to the causation issues central to IBM's motion for summary judgment." *Id.* at 64. Indeed, Delaware law clearly further supports this proposition. See, e.g., *Bryant v. Delmarva Power & Light Co.*, C.A. No. 89C–08–070, slip op. at 26 (Del.Super.Oct. 2, 1995) (industry "custom" does not

establish a legal duty). Thus, as in *Schneck*, this Court finds that plaintiffs have failed to establish the requisite element of causation through submission of the aforementioned documents.

Before more completely addressing plaintiffs' exhibits propounded for the availability of alternative keyboard design, the Court feels compelled to comment upon the morass of materials it waded through in plaintiffs' appendices. Most of these documents have been submitted without any proper foundation, contain hearsay and are irrelevant. In deciding a motion for summary judgment under [Rule 56](#), only admissible evidence is to be considered. Drowning the Court in a tidal wave of paper does not mean that a genuine issue of material fact exists.

As in *Schneck*, plaintiffs' herein have submitted materials regarding instructions, warnings and alternative keyboard products of other manufacturers. D.I. 324–325, Ex. 18–20; D.I. 326, Ex. 59–63. *Schneck* found such evidence lacking probative value and inadmissible under [Fed.R.Evid. 402](#). *Schneck* at 64.


An issue similar to that presented herein was also addressed in *In re Richardson–Merrell, Inc., Bendectin Prods. Liab. Litig.*, a product liability case involving the prescription drug  *Bendectin*. 624 F.Supp. 1212 (S.D.Ohio 1985), *aff'd*,  857 F.2d 290 (6th Cir.1988), *cert. denied*, 488 U.S. 1006 (1989). In *Richardson–Merrell*, the plaintiffs offered warning labels on nonprescription drugs produced by other manufacturers. *Id.* at 1231. The court excluded those labels as irrelevant:

The threshold requirement of relevancy simply was not met. The fact that warnings were placed on these three over-the-counter (nonprescription drugs) by manufacturers other than the defendant did not make the existence of a fact of consequence more or less probable.... [The evidence] is not germane to the single issue of whether Bendectin causes birth defects.



*58 *Id.* at 1230–31.

In this case, as in both *Schneck* and *Richardson–Merrell*, other manufacturers' warning labels have no probative value. The rationales underlying the inclusion of warning labels and/or instructions by other manufacturers, or their production of alternative keyboards, are unknown to this Court. While they *may* relate to safety and causation issues, they could just as likely reflect an action propelled by an overcautious attorney's advice. As such, the probative value of other manufacturers' warning labels is very dubious at best, and the Court must find them inadmissible.

Moreover, even if the other manufacturers attached such warning labels, included instructions with their packaging materials, or developed alternative keyboards premised upon an actual determination of risk and causation relating to their own keyboards, these activities would be meaningless with regard to the risks associated with IBM's keyboards.

See *Schneck* at 66;  *Richardson–Merrell*, 624 F.Supp. at 1231 (excluding as irrelevant warning labels of other manufacturers because “the warnings on these drugs are ambiguous, at best, when attempting to infer the purpose for which the warnings were designed.”). Without the appropriate factual foundation demonstrating the purpose of the warnings, instructions, and alternative keyboards, not to mention the circumstances under which they are provided, such evidence is irrelevant. *Id.* In light of the discussion herein, those warnings/instructions and alternative keyboard designs by other computer equipment manufacturers which plaintiffs proffer as evidence of causation and IBM's duty to warn are irrelevant and inadmissible pursuant to [Fed.R.Evid. 401](#) and [402](#).

Most significantly, those warning/instruction and alternative keyboard design materials submitted by plaintiffs are inadmissible under the exclusionary hearsay rule, and unredeemed by any hearsay exception. See [Fed.R.Evid. 805](#). Upon a document proffer, the proponent must establish that both the document itself and the hearsay statements contained therein fit within an exception to the hearsay rule. *Id.* The materials regarding other manufacturer's warnings, instructions, and alternative keyboards are undeniably out-of-court statements proposed by plaintiffs for the truth of the matter asserted—i.e., that keyboards can cause not only injury, but the injuries in this matter. As such, they are inadmissible hearsay. See [Fed.R.Evid. 803](#); *Richardson–Merrell*, 624 F.Supp. at 1232 (“The warnings are out-of-court statements offered to prove the truth of the matters asserted.... The warnings are in fact inadmissible hearsay.”).

Indeed, the various exhibits submitted by plaintiffs also contain an *additional* layer of hearsay, where included are assertions by unknown people about the risks of keyboard operation. As defendant is unable to cross-examine those people, their statements are inadmissible. See  *Cedeck v. Hamiltonian Federal Say. & L. Ass'n*, 551 F.2d 1136, 1138 (8th Cir.1988) (statements containing a reiteration of what some unknown person told the declarant were excluded as hearsay);  *Carden v. Westinghouse Elec. Corp.*, 850 F.2d 996, 1002 (3rd Cir.1988) (following *Cedeck*).

***59** The Federal Rules of Evidence on this matter are unequivocal and allowing plaintiffs to introduce the aforementioned materials would in effect circumvent their obligation to establish the qualifications of unidentified people to render expert testimony under [Fed.R.Evid. 702](#), and the factual foundation for those opinions under [Fed.R.Evid. 703](#), as well as preclude defendant's cross-examination of such experts.

Moreover, no testimony proposed by plaintiffs' experts establishes that any of the alternative designs would have prevented the injuries plaintiffs claim resulted from their use of IBM keyboards. D.I. 310, A-90, 239, 246. Specifically, Dr. Bleeker, plaintiffs' only specific causation expert, admittedly cannot determine whether alternative design keyboards would eliminate, prevent or even reduce incidents of CTS. D.I. 310, Ex. A-90.

Therefore, for all reasons contained herein, the Court must deny admission (and consequent consideration) of all

those documents regarding other manufacturers' warnings and instructions related to keyboard use, as well as those documents showing alternative keyboard design, which plaintiffs have proffered. ⁵⁸

CONCLUSION


For the reasons contained herein, it is recommended:

1. That defendant's motion to exclude plaintiffs' experts, Drs. Kroemer and Cunitz, on the basis of *Daubert/Paoli II* standards should be GRANTED.
2. That defendant's motion to exclude plaintiffs' experts, Drs. Punnett and Bleeker should be DENIED.
3. That defendant's motion for summary judgment on plaintiff Bowers' claim as being time-barred by the operation of [10 Del. C. § 8119](#), the applicable statute of limitations, should be GRANTED.
4. That defendant's motion for summary judgment on the issues of design defect and duty to warn should be GRANTED. As a result, since plaintiff George Allen's claim is derivative and plaintiffs' claim for punitive damages is not an independent claim, but requires a verdict of compensatory damages in their favor before exemplary damages can be considered and awarded, it is further recommended that plaintiffs' entire action be DISMISSED.

All Citations

Not Reported in F.Supp., 1997 WL 34501372

Footnotes

- 1 Plaintiff Mathis initially filed under her maiden name of Bowers. For the purposes of this opinion, plaintiff is referred to by her maiden name of Bowers. D.I. 322 at 1.
- 2 Plaintiff Susan Allen is joined by her husband, George, in this action. For the purposes of this Report and Recommendation, the Court solely refers to Ms. Allen as the plaintiff, addressing her as "Allen."
- 3 Plaintiffs' alleged medical conditions are commonly classified as "repetitive stress injuries" ("RSI"), currently the subject of numerous actions against computer manufacturers across the nation.
- 4 The claims for loss of consortium and punitive damages are dependent upon the survival of the negligence claim. See, e.g.,  *Farrall v. Armstrong Cork Co.*, 457 A.2d 763, 770 (Del.Super.1983) (consortium claim is derivative); *E.I. duPont de Nemours and Co. v. Admiral Ins. Co.*, C.A. No. 89C-AV-99 slip op. at 21 (Del.Super. July 14, 1994) (punitive damages is derivative).

- 5 As prep cook for H.A. Winstons, Allen worked seven hours a day, five days a week. D.I. 311, Ex. A-694-96.
- 6 As a receptionist, Allen works four-and-a half hours per day, five days a week. D.I. 311, Ex. A-721-22.
- 7 [Fed.R.Evid. 702](#) specifically provides that:
If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.
- 8 The *Paoli II* court identified several factors to consider in the preliminary determination of the reliability of scientific testimony, including, but not limited to:
(1) whether the method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.
- [Velasquez](#), 64 F.3d at 849 n. 8 (quoting [Paoli II](#), 35 F.3d at 742 n. 8). As noted by the Third Circuit, *Daubert* includes two factors not previously applied by the court in *Downing* (cited in the body of this Report and Recommendation at 12), those being whether a method produces a testable hypothesis and the existence of standards controlling the technique's operation. However, *Daubert* fails to include in its list a number of factors applied in *Downing*—the extent of the expert's qualifications, the relationship of a technique to “more established modes of scientific analysis,” and the “non-judicial uses to which the scientific techniques are put.” [Downing](#), 753 F.2d at 1238-39; [Daubert](#), 113 S.Ct. at 2796-97. Since *Daubert* did not specifically disavow any factors contained in *Downing*, a district court is directed to consider all factors included in *Daubert* and *Downing* “as well as any others that are relevant.” [Paoli II](#), 35 F.3d at 742.
- 9 As noted by the Third Circuit in *Downing*, the analysis under [Rule 702](#) overlaps with the considerations under [Rule 403](#), but allows “some room for [Rule 403](#) to operate independently.” [Paoli II](#) 35 F.3d at 746. As will be addressed later in this Report and Recommendation, the application of [Rule 403](#) in a pre-trial setting is somewhat limited.
- 10 However, as noted in *Paoli II*, the *Daubert* holding that [Rule 702](#) operates as the primary focus of a court's gatekeeping function indicates that exclusion of an expert's testimony under [Rule 403](#) would be rare in spite of the Third Circuit's finding that [Rule 403](#) provides judges with greater power over experts than ordinary witnesses. Both rules provide slightly more judicial substantive power than usually exists under [Rule 403](#) to determine that the evidence is more prejudicial than probative. [Paoli II](#), 35 F.3d at 747 n. 16.
- 11 Plaintiffs' citations to personal injury “asbestos cases,” where Delaware courts have held that the [Section 8119](#) statute of limitations is triggered when the plaintiff is chargeable with the knowledge that his condition is attributable to asbestos exposure are inapplicable to the case at bar. [See.g., Collins v. Pittsburgh Corning Corporation](#), 673 A.2d 159, 162 (Del.1996). Asbestos-related medical conditions, of which there are a variety, can manifest symptoms, such as shortness of breath or coughing, well in advance of the detection of asbestos in the lungs. Asbestosis is thus a “latent” disease which cannot be traced to an asbestos manufacturer until the asbestos is discovered in the lungs. Further, under Delaware law the courts have recognized that a different beginning of the limitation period may be applicable for different conditions (e.g., pleural thickening, asbestosis, lung cancer) having different manifestation dates. As a result, [Section 8119](#) may operate to bar a claim for one type of asbestos-related condition, such as pleural thickening, but not for another, that is, asbestosis. [Sheppard v. AC & S Company](#), 498 A.2d 1126 (Del.Super.1985), *aff'd sub nom.*, [Keene v. Sheppard](#), 503 A.2d 192 (Del.1986).

- 12 In his July 31, 1990 letter to Dr. Theodore Michel, Bowers' HMO physician, Boulos recounted Bowers' July 26, 1990 reported medical history of the pain in question: "About two months ago [Bowers] started experiencing numbness, paresthesias and pain in both her hands...." D.I. 310, Ex. A-777.
- 13 Dr. Kroemer, a generic and not plaintiff-specific expert, was originally assumed by defendant as being offered as a "state-of-the-art" expert, who would not be addressing design defects, and would limit his opinions to those allowed and testified to in *Schneck*. During his *in limine* hearing, two additional reports by him were identified by plaintiffs' counsel as part of his opinion—the reports of August 17, 1995 and September 15, 1995—both of which dealt with his analysis of alleged defects in the design of generic keyboards. D.I. 303 at 28–57. A substantial amount of the Kroemer *in limine* transcript is devoted to plaintiff's counsel's failure to adequately identify the areas (state-of-the-art and design defects) on which Kroemer would testify, and counsel's similar failure to identify these two reports. D.I. 359 at 28–57, 118–144, 177–182. During this colloquy, it was learned that plaintiffs' counsel had provided a copy of reports to the Court, after the September 16, 1996 hearing on whether the *in limine* hearings were required, but provided the defense with only a copy of the August 17, 1995 report. D.I. 359 at 178. Of note, neither report was specifically referenced in plaintiffs' brief. The previous information provided regarding Kroemer's proffer included a March 30, 1992 report expressing his opinion on the state-of-the-art or cumulative trauma disorders, attached to which was a CTD bibliography review, an updated bibliography review on keyboarding dated February 5, 1994 (D.I.310, Ex. A-313–462), and another bibliography update of February 28, 1995 on articles relating to keyboards. D.I. 329, Ex. 53. Neither the March 30, 1992 report nor literature abstracts contained any opinion by Kroemer on alleged defective design of any keyboards, including the abstract of his own 1964 and 1972 articles. None of this material contained or referenced any opinion expressed by Kroemer as to defective design nor the measures/methods available for improvement. As a result, neither his methodology nor the scientific reliability regarding these issues were provided. However, the August 1995 report titled *Ergonomic Deficiencies of Conventional Keyboards* appears to express his opinions on keyboard designs. D.I. 352, Ex. 77. Similarly, his subsequent report of September 15, 1995 (*Design Deficiencies of Conventional Keyboards*) contained Kroemer's opinions on design defects. Since Kroemer had previously been identified or described as an ergonomist and human factors engineer, concerned with biomechanical and applied physical aspects involved in workplace design, planning, set-up and psychology, and since his August 1995 report had been provided, he was allowed to testify as to his opinion on design defects limited to his August 1995. Kroemer's September 1995 report was not admitted and no examination on that report was permitted.
- 14 The *Schneck* decision is now on appeal to the Third Circuit.
- 15 The Court will, however, address plaintiffs' references to court decisions on this issue in other jurisdictions which allowed plaintiffs' experts' testimony—to this limited degree. Plaintiffs' references to *Smith v. IBM* and *Davis v. NCR* essentially are inapplicable to the matter at hand. *Smith*, Civ. No. 94–34–P–C, U.S.D.C. (D.Me. Jan. 19, 1996); *Davis*, No. 9496092/CL183437 slip op. (Cir.Ct.Balt.City May 3, 1996). Neither case presents a detailed *Daubert* analysis as does *Schneck*, and both fail to address *Frye*. Moreover, the *Smith* court entertained several arguments rejected by the court in *Schneck*, such as defective design and duty to warn. In addition, contrary to plaintiffs' argument, the *Davis* court rejected plaintiffs' claim of punitive damages against IBM. Finally, plaintiffs' reliance on *Davies v. Datapoint* also is misplaced in light of that court's exclusion of Kroemer's testimony and finding that no design defect existed in the computer keyboards in question. *Davies*, Civ. No. 94–56–P–DMC (D.Me. Oct. 31, 1995).
- 16 However, Kroemer's abstracts of his literature search clearly includes articles that have not been subject to any peer review process. D.I. 359 at 60.
- 17 In *Schneck*, Kroemer's conclusion included a reference to keyboard design. However, he failed to specify any design defect in the IBM machines which would support plaintiffs' claim that they caused injury. See *Schneck* Op. at 24–25. Thus, with particular regard to plaintiffs' failure to warn claim, Kroemer's testimony in the *Schneck* case was limited to the proposition that it was "well-established" that typing itself causes "cumulative trauma disorders." D.I. 310, Ex. A-352.

- 18 IBM argues that Kroemer's testimony that scientific validity means simply "shedding light on a notion," highlights the unreliability of his testimony and the methodology used in preparing his reports. D.I. 310, Ex. A-200, D.I. 309 at 12. See also, D.I. 359 at 9,77.
- 19 As evidence of Kroemer's unscientific methodology, defendant highlights the "catch-basin" nature of his report on "keyboard design," "keyboard use," and "cumulative trauma disorders," whereby a piece of literature was not required to discuss both "keyboard design" and "cumulative trauma disorders" to be included in his reports. D.I. 309 at 12, D.I. 310, Ex. A-322 (citing Flowerdew, R.E. and Bode, O.B., *Tenosynovitis in Untrained Farm-Workers, Medical Memoranda, Bawan [sic] Medical Journal* (1942)); (see also, D.I. 310, Ex. A-329) (citing Conrad, R. and Longman, D.J.A., *Standard Typewriter v. Chord Keyboard—An Experimental Comparison*, 8 *Ergonomics* 77-88 (1965)). Further, criticisms by IBM of Kroemer's unscientific approach to the issue at hand center on the witness' deposition response (cited in relevant part) to the inquiry of whether any of the examined literature concludes that keying causes "cumulative trauma disorders":
- ... my point of interest in this whole procedure is what are the ergonomic aspects of keyboards that may lead—that have suspected symptoms or, in fact, may have been fact to [sic] lead to cumulative trauma disorders. If we then depart with the—depart from that ergonomic point of view, all we need to do is start, in fact, in page 1 of Exhibit No. 6 [Kroemer Supp. Report] and read the synopsis of what Osler said in 1892. And if you read this, it says: The continuous and excessive use of muscles in performing a certain movement may be followed by an irregular, involuntary spasm, cramp and so forth. How much more clearly can it be established ... that more than one hundred years ago that certain activities such as might be required on a keyboard can constitute a continuous and excessive use of muscles that result in a disorder. And that will be a typical example in the way of which I would try to answer your question in terms of what does [sic] ergonomists read out of that literature.
- D.I. 309 at 13; D.I. 310, Ex. A-206.
- 20 To the extent, if at all, that the August 1995 report is dependent upon his prior report and abstracts, Kroemer is still uncertain whether his methodology has been followed within his profession.
- 21 In *Dennis v. Pertec Computer Co.*, a similar product liability action, plaintiffs proffered Kroemer's expert testimony regarding "the relationship between the biomechanics of keystroking and upper extremity disorders." 927 F.Supp. 156, 160 (D.N.J.1996). The court excluded Kroemer's testimony, concluding that "Kroemer's (sic) unrecorded mental methodology amounts to nothing more than unsupported speculation." *Id.* at 161. While plaintiffs in the case *sub judice* argue that the *Dennis* court's decision was "clearly overreaching" (D.I.322), and that the record indicates the reliability and peer review of Kroemer's research and opinions, this Court holds otherwise for the reasons discussed herein.
- 22 This review was conducted via a key word search on a computerized database of literature on occupational safety and health, and supplemented by consultation with other experts in the subject field. D.I. 350 at 11-12.
- 23 This reference group was utilized by one of the studies upon which Punnett relied. D.I. 350 at 23-34, 36-43.
- 24 Although Punnett began her review with twenty studies, she relied on only eleven. Of those, Punnett deemed the following seven studies to have "no or only very minor methodological flaws that might affect interpretation of their results": *LA Times*, *Newsday*, *U.S. West*, *Knave*, *Rossignol*, and *Sauter*. D.I. 311, Ex. A-651, Ex. A-655-58. The remaining four of the eleven, conducted by *Hunting*, *Kamwendo*, *Maeda*, and *Starr*, "had relatively minor weaknesses, not serious enough to invalidate them completely or that only affected some of the study findings." D.I. 311, Ex. A-651, A-656-59.
- 25 Under Punnett's definition, such disorders are "a group of clinical syndromes including nerve compression disorders (such as carpal tunnel syndrome), tendon inflammations and related conditions (tenosynovitis, epicondylitis, bursitis of the shoulder, etc.), as well as non-specific pain or paresthesia and conditions that some clinicians describe as myositis, fibromyalgia, focal dystonia, and other diagnoses that are less well standardized." D.I. 311, Ex. A-629. Defendant argues that Punnett's definition excludes any reference to, or discussion of, a scientifically defined disease entity. D.I. 309 at 14.

- 26 Punnett's additional analyses with the aforementioned low-risk external group displayed an even stronger contrast in risk of hand and wrist symptoms and physical findings between the exposed group and "non-exposed," low-risk external group. D.I. 350 at 23–34, 36–43.
- 27 In *Schneck*, the defendant made the same arguments now cited. See *Schneck* Op. at 27–28.
- 28 Trichopoulos' testimony stems from the *Schneck* case, during which IBM offered the doctor's expert opinion to challenge the quality and reliability of the studies upon which Punnett based her report at issue. D.I. 334 at 15. Currently submitted correspondence between the parties in that action indicate that the *Schneck* plaintiffs chose to forego cross-examination of Trichopoulos in favor of submitting a responsive supplemental report by Punnett herself. D.I. 344, Ex. D–G. In the case at bar, defendant included the aforementioned correspondence as exhibits to the Reply Brief (D.I.334, Ex. D–G), but inexplicably failed to submit Trichopoulos' actual affidavit and deposition until this Court queried as to their location in the exhibits, where the documents were alluded to on a number of occasions and are apparently relevant to the matter at hand. While it may be argued that defendant's late submission of these materials is inappropriate, the Court will consider this evidence, which has no docket entry number and is instead cited as "Aff. of Trichopoulos," deeming such latitude in the interest of justice. Attached to Trichopoulos' affidavit dated January 30, 1994 as Exhibit A is a 17–page assessment of the evidence concerning a possible link between keyboard operation and data entry tasks and musculoskeletal disorders, which includes his criticism of Punnett's analysis, as Exhibit B, his deposition of September 13, 1994 and as Exhibit C a supplement dated July 7, 1995 to his original report contained in Exhibit A.
- 29 According to Trichopoulos' deposition testimony, the doctor characterizes the aforementioned differences in basic premises as what he considers to be the lack of an independently defined and generally recognized disease entity that is being studied, as well as the criteria for causation as they were applied in a particular situation. Aff. of Trichopoulos, Ex. B at 62.
- 30 While defendant in this action argues that the *Schneck* Court improperly considered Zoloth's testimony, where the expert earlier had been withdrawn by plaintiffs in that case, this Court finds that plaintiffs Allen and Bowers properly submitted Zoloth's affidavit for consideration on the issue of the admissibility of Punnett's expert witness testimony.
- 31 In *Schneck*, Zoloth argues that "[t]he IBM lawyer is mistaken in asserting that epidemiology can only concern itself with 'disease entities.' While the symptom complexes reported in several of the studies represent distinct 'disease entities' (with specific I.C.D. codes), epidemiology does apply to many *real* non-disease entities (e.g., low birth weight, suicide, violence ...)." D.I. 327, Ex. 40 at ¶ 17 n. 1.
- 32 Further, Zoloth opines that "these symptom complexes are not only representative of distinct 'disease entities,' but are reportable on OSHA 200 logs, and are compensable under the Workers Compensation statutes of many states." D.I. 327, Ex. 40 at ¶ 17 n. 2.
- 33 In her deposition, Bleeker outlined the issues she would address in her expert testimony, including causation and warnings. According to the doctor, her opinions do not center upon a particular keyboard, such as the IBM keyboard design now at issue, but are more generalized. D.I. 310, Ex. A–3 at 10.
- 34 Bleeker admittedly lacks expertise in keyboard design and required and appropriate warnings. D.I. 310, Ex. A–92 at 295, Ex. A–73 at 297–99. Nor is she being offered as an expert to testify in those areas. D.I. 322 at 25.
- 35 Bleeker suggested that the work of Punnett's to which she was referring may have been in a chapter of the Journal of Hand Surgery, but also noted that she had heard Dr. Punnett present the data at a meeting in San Francisco. Further discourse between Bleeker and defense counsel indicates that the Punnett work in question is the same material published from the proceedings of the 1994 Bethesda, Maryland meeting of the American Orthopedic Surgeons, which is the basis of Dr. Punnett's testimony in this case (the Punnett Report).
- 36 There is no doubt that this Court would have preferred a broader base of specifically cited literature and a more defined, delineated methodology with regard to general causation. And, indeed, Bleeker's *in limine* hearing testimony suggests that she reaches her conclusions upon consideration of numerous scientific articles, upon which, unfortunately, counsel for either party failed to elicit elaboration. However, that notwithstanding,

Bleeker's primary reliance on Punnett's Report is sufficient for the conduct of a *Daubert/Paoli II* analysis to determine the admissibility of her expert testimony.

37 Plaintiffs maintain that having eliciting their social and occupational histories, Bleeker was thus fully aware of both the nature and extent of plaintiffs' exposure to defendant's products, and of any other factors which might be medically relevant to a determination of causation in their cases. D.I. 322.

38 In her *in limine* testimony, Bleeker commented that she had, in fact, noted during her first examination of Allen that the plaintiff had been involved in two motor vehicle accidents in 1989 and 1993, which predated the onset of her CTS symptoms and eliminated them as a cause. D.I. 353 at 19–21.


39 As noted previously, plaintiffs maintain that having eliciting their social and occupational histories, Bleeker was thus fully aware of both the nature and extent of plaintiffs' exposure to defendant's products, and of any other factors which might be medically relevant to a determination of causation in their cases. D.I. 322.




40 With regard to this issue of “general” causation, Bleeker also stated in deposition testimony that the causal link between keyboard use and CTS is “clearly accepted” among medical professionals in the area of occupational medicine. D.I. 330, Ex. 65 at 85–87. The doctor further addressed the role of keyboard design, stating that “keyboard designs ... have adversely affected the health of ... users” (*Id.* at 276), with specific criticism directed at such design factors as (1) “the amount of force that is required to depress” the keys (*Id.* at 276); (2) “how the keyboard is actually angled,” placing the hands in “ulnar deviation” (*Id.* at 277); (3) the overloading of tasks on a single hand (*Id.* at 276); and (4) the lack of instructions regarding “how one is to use the keyboard.” *Id.* at 277.


41 In his assessment of whether warnings were merited, Cunitz applied a “reasonable suspicion of harm standard,” which, while his own wording, was argued by the human factors psychologist as being entirely consistent with the threshold standard widely accepted in the human factors field. D.I. 349 at 38.

42 Plaintiffs and defendant submit contradictory decisions from other jurisdictions admitting and excluding, respectively, Cunitz's testimony as a “warnings” expert. While the Court has reviewed the opinions and the reasoning contained therein, which in some instances follows the rationale espoused by this Court, it recognizes that the opinions cited do not serve as controlling case law.

43 The *Schneck* court also rejected plaintiffs' arguments that the reliability of a physician's testimony based on differential diagnosis, the testimony of their design defect expert and the issue of causation are subject to judicial notice and the court therefore need not perform the *Daubert* analysis. See *Schneck* Op. at 50–52.

44 Plaintiffs' reliance upon *Towe* is completely unsubstantiated. As previously noted in IBM's argument, *Towe* addressed a motion to dismiss a breach of warranty claim under Super. Ct. Civ. R. 12(b)(6), which is similar to Fed.R.Civ.P. 12(b)(6), wherein the Superior Court interpreted the application of its rule finding that a complaint will only be dismissed for failure to state a claim if “under no set of facts which could be proven to support the claim asserted would plaintiff be entitled to relief.”  *Towe*, 290 A.2d at 658. This interpretation is similar

to this Circuit's application of Rule 12(b)(6).  *Conley v. Gibson*, 355 U.S. 41, 45–6 (1957);  *Colburn v. Upper Darby Twp.*, 838 F.2d 663, 665–66 (3rd Cir.1988) quoting  *Estate of Bailey by Oare v. County of York*, 768 F.2d 503, 506 (3rd Cir.1985). Although the plaintiffs in *Towe* had not spelled out “all of the details of their cause of action,” their complaint would not be dismissed at the initial stages of the action because it gave “general notice as to the nature of the claim asserted against defendant.” *Id.* This is not the standard for Rule 56 which requires a showing of a genuine issue of material fact, as discussed at pp. 7–8 herein.

45 In a number of recent decisions, this jurisdiction and others have rejected similar design defect claims. To wit, in *Finley v. NCR Corp.*, the court granted summary judgment to defendant on plaintiffs' design defect claim, where plaintiffs' experts failed to establish a verifiable scientific link between keyboard use and CTS. C.A. No. 92–5242 (D.N.J. Jan. 22, 1996). The Fourth Circuit ruled likewise in *Mastalski v. IBM Corp.*, where it upheld the district court's grant of summary judgment in favor of IBM against plaintiff's claim of injury due to defective design of her  IBM keyboard. 1992 WL 207789, at *6 (4th Cir.1992). Finding that plaintiff's expert had failed to establish any scientifically verifiable link between keyboard use and plaintiff's injury, the *Mastalski* court concluded that “[a]n injury resulting from a requirement to maintain long hours and a fast pace

would be more akin to harm from the over consumption of an otherwise relatively safe and non-defective product, such as a tennis racquet.” *Id.*

46 Plaintiffs further fail to identify those applicable standards and IBM's alleged subsequent deviation therefrom.
47 Those broad categories were too many keys, unergonomic arrangement of keys and insufficient space to rest wrists. *Schneck* at 11.

48 As can best be discerned from the record, Bleeker's comments would include the type of alternative keyboard designs and studies discussed by Kroemer. D.I. 359 at 150–152, 155.

49 As emphasized in *Reiff*, the existence of alternative designs, such as split-angle keyboards, alone without ergonomic or medical literature demonstrating such devices either reduce typing discomfort or the risk of developing musculoskeletal injuries, are insufficient to prove design defect. *Reiff* at 13–14.

50 Plaintiffs recite a litany of IBM internal memoranda and company-sponsored studies which examine and address the increased incidence of repetitive stress injury (“RSI”) among keyboard operators. It is clear that plaintiffs view this evidence as “the smoking gun.” D.I. 322 at 6–15. While the Court in no way shares this perception, as shall be elaborated upon forthwith, plaintiffs' proffers are highlighted. To wit: (1) a 1990 IBM publication discusses carpal tunnel syndrome and its potential relationship to keyboard work *and* workstation design. D.I. 323, Ex. 5; (2) in 1984, an IBM VDU Task Force reported on the increased incidence of RSI among Australian keyboard operators. D.I. 323, Ex. 6 and 7; (3) an IBM senior engineer associated “[t]he CTD problem” to “keyboarding with VDT's” (D.I.323, Ex. 10), and acknowledged that “repetitive motion trauma” puts IBM at risk for “increased [legal] exposure” as a result of “increased general awareness.” D.I. 323, Ex.11; and (4) Richard S. Hirsch, Ph.D., a manager of IBM's Human Factors Engineering Department, appeared before nationwide legislative bodies in the 1980s, representing that the use of VDTs was absolutely safe and that IBM's own employees had many years of experience using VDTs with no resulting adverse health effects, although Hirsch was cognizant of the alleged connection between the reported ailments and keyboard engineering and design. D.I. 323, Ex. 14. Plaintiffs also argue that, in addition to what IBM actually knew about the relationship between VDTs/keyboard use and RSIs, IBM *should have known* about the general propensity of its computer keyboard products to cause such injuries as suffered by Allen and Bowers in light of the expert reports available on the subject and defendant's own internal experiences. Specifically: (1) recognized epidemiologist Dr. Stephen Zoloth had compiled a report establishing that medical and scientific literature dating back several decades contained numerous learned articles by respected authorities which discussed the severity of injuries resulting from keyboard use. D.I. 324, Ex. 21; and (2) IBM's former Director of Health, Dr. O.B. Dickerson, purportedly acknowledged significant numbers of upper tenosynovitis cases resulting from operation of the current [QWERTY] keyboard, which caused unnecessary tension on the hands, wrists and forearms and could be redesigned to reduce such medical symptoms. D.I. 324, Ex. 23. Finally, noted RSI authority Dr. Emil Pascarelli has testified that design flaws contributing to CTS-type injuries occur generally in all manner of QWERTY designed keyboards (such as those manufactured by IBM), and that RSI to a significant degree is entirely preventable if the keyboard user is *given appropriate warnings* regarding rest breaks, ergonomic workstation setup and typing technique. D.I. 324, Ex. 22.

51 Under Delaware law, the existence of a duty to warn is a question of law for the court. *Macey v. AAA–1 Pool Builders and Serv. Co.*, C.A. No. 88–C–JN–10, slip op. at 5.

52 A proof encoder is a device used by banks to encode information on checks. *Hopkins*, 1994 WL 757510, at *1.

53 Further, according to Bleeker, when performing an ergonomic analysis, she considers posture, positioning of the upper body, including the extremities, back, shoulders and head, layout of the workstation, availability of break time versus continuous typing, amount of muscle force employed, other types of work activity, intensity, repetition, and other factors—in determining the contribution to and the alleviation of upper extremity disorders, such as carpal tunnel syndrome. D.I. 353 at 15–19. As noted previously herein, such testimony is insufficient to prove the legal requirement that “the risk associated with the use of defendant's product is something more than the physical activity required to use it.” *Reiff* at 16.

54 And, in fact, none of plaintiffs' remaining experts can say, within a reasonable degree of medical certainty, that some undefined warning would have prevented the particular medical problems suffered by plaintiffs.

- 55 Parenthetically, the Court notes that Bleeker's testimony, although satisfying the *Daubert/Paoli II* test of admissibility may not meet the legal standard of proximate cause. For example, as noted previously herein, Bleeker's testimony that plaintiffs' CTS developed from keyboard use primarily rests upon a temporal association between increased typing and development of their respective symptoms. Further, she recognizes a number of other factors that contribute to the development of CTS. D.I. 310, Ex. A-73 at 298; D.I. 353 at 15-19. While a temporal association is sufficient for accepted scientific methodology, reliability and fit under 702, it does not necessarily equate to proximate cause. Being a substantial factor may meet scientific methodology considerations but does not meet the "but for" requirement of proximate cause. *Culver v. Bennett*, 588 A.2d 1094, 1096, 1098 (Del.Supr.1991).
- 56 As was pointed out by defendant and recalled by the Court, during at least one status/discovery conference, IBM represented a willingness to stipulate to such knowledge and information.
- 57 CTD (cumulative trauma disorder), RSI (repetitive stress injury), and CTS (carpal tunnel syndrome).
- 58 The bases for finding other manufacturers' warnings and instructions and alternate keyboard designs inadmissible are applicable to plaintiffs' other exhibits.

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